Attachment 14

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AMENDED IN ASSEMBLY APRIL 7, 2005

AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 71

Introduced by Assembly Members Chan and Frommer (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, and Pavley)

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office ~~to establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions, establish a Web site to provide up-to-date information to the public about adverse drug reactions, maintain a database of adverse drug reaction reports, and act as a liaison with all appropriate parties to ensure the speedy and accurate flow of information about important drug safety issues~~, *among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs, to disseminate information to*

health care professionals and consumers through an Internet Web site, to request assistance from the University of California and California State University, and to rely on systematically reviewed evidence-based research.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Since 1997, when the United States Food and Drug Administration (FDA) allowed drug manufacturers to advertise directly to consumers, the amount spent on advertising has risen dramatically.

(b) According to the United States General Accounting Office (GAO) report, the pharmaceutical industry spent $2.7 billion in 2001 on direct-to-consumer advertising. A December 6, 2004, New York Times report states that such spending has reached $3.8 billion.

(c) According to the same GAO report, while overall spending on drug promotion was less than spending on research and development ($19.1 billion versus $30.3 billion), spending on direct-to-consumer advertising is increasing at a faster rate than overall drug promotion spending or spending on research and development. Between 1997 and 2001, the increase in direct-to-consumer advertising was 145 percent compared to a 59 percent increase for research and development.

(d) Although the FDA is responsible for postmarket surveillance of prescription drugs, numerous concerns have been raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time,

both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

(h) Californians do not have a reliable central repository of information about prescription drug safety and effectiveness.

(i) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

(j) The Oregon Drug Effectiveness Review Project is developing information that could be used for a central repository of information about prescription drug safety and effectiveness. The State Department of Health Services, CalPERS, and the California Healthcare Foundation all participate in the Oregon Drug Effectiveness Review Project.

(k) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. *(a)* There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, *to provide Californians with information on the safety and effectiveness of prescription drugs*:

~~(a) Establish a toll-free telephone number for the purpose of receiving reports of adverse drug reactions.~~

~~(b) Establish a Web site to provide up-to-date information to the public about adverse drug reactions.~~

~~(c) Maintain a database of adverse drug reaction reports.~~

~~(d) Act as a liaison with all appropriate parties, including the United States Food and Drug Administration, drug manufacturers, pharmacists, physicians, health care providers, and consumer drug safety organizations, to ensure the speedy and accurate flow of information about important drug safety issues.~~

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs.

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved.

(3) Ensure that the dissemination of information is done in a culturally competent manner.

(4) In selecting therapeutic classes of drugs about which to develop information, give priority to therapeutic classes that have one or all of the following characteristics:

(A) Classes of drugs for which there have been recently published reports of safety concerns.

(B) Classes of drugs that have been advertised on television directly to consumers.

(C) Classes of drugs for which there is recently published systematically reviewed evidence-based research.

(5) Request appropriate units of the University of California and the California State University to provide assistance.

(6) Rely on systematically reviewed evidence-based research.

(b) The office shall have the authority to review the formularies of all state-funded programs for their use of systematically reviewed evidence-based research.

(c) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.

111657.1. For purposes of this article, the following terms have the following meanings:

(a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.

(b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to

estimate the comparative effectiveness and safety of health care treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 71 **VERSION: AMENDED APRIL 7, 2005**

AUTHOR: CHAN et. al. **SPONSOR: CHAN**

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACEUTICALS: ADVERSE DRUG REACTIONS: OFFICE OF CALIFORNIA DRUG SAFETY WATCH

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

1) Establishes the Office of California Drug Safety Watch (office) within the Department of Health Services (DHS). (H&S 111657 Added)

2) Requires the office to do all of the following:

a. Establish a central repository of information about the safety and effectiveness of prescription drugs.

b. Disseminate information to health care professionals and consumers through an Internet Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

c. Assure that the dissemination of information is done in a culturally competent manner.

d. Request units of the University of California and the California State University to provide assistance.

e. Rely on systematically reviewed evidence-based research.

f. Give priority, when selecting therapeutic classes of drugs about which to develop information, to therapeutic classes that have one or all of the following characteristics:

i. Classes of drugs in which there have been recently published reports of safety concerns.

ii. Classes of drugs that have been advertised on television directly to consumers.

iii. Classes of drugs for which there is recently published systematically reviewed evidence-based research.

(H&S 111657 Added)

3) Authorize the office to review the formularies of all state-funded programs for their utilization of systematically reviewed evidence-based research. (H&S 111657 Added)

4) Requires the office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication. (H&S 111657 Added)

5) Defines the following terms:

a. Evidence-based research to mean prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.

b. Systematically reviewed to mean review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of healthcare treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.

(H&S 111657.1 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the Federal government to take action to warn the public about potentially dangerous drugs.

2) Necessity for Bill? The intent of this legislation is to provide Californians with a reliable central repository of information about prescription drugs safety and effectiveness. This type of information is currently available through many sources, including the FDA, the Oregon Drug Effectiveness Review Project, Consumers Union [Reports], and the AARP; all of which have Web sites that consumers and healthcare professionals can access for information. Given that reliable information is available, perhaps it would better and less costly for the Administration to direct DHS to establish a Web site with links to information on drug safety, rather than passing legislation that would require to DHS to establish a new program that essentially duplicates what is being done by other entities.

3) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

SB 380 (Alquist) Drugs: Adverse event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.)

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and will be amended for other purposes.

4) History.

2005	
Apr. 11	Re-referred to Com. on HEALTH.
Apr. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Feb. 15	Re-referred to Com. on HEALTH.
Feb. 11	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Com. on HEALTH.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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BILL ANALYSIS
AB 71

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 71 (Chan) - As Amended: April 7, 2005

SUBJECT : Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

SUMMARY : Establishes the Office of California Drug Safety Watch within the Department of Health Services (DHS) to serve as a central repository of information on prescription drug safety and effectiveness. Specifically, this bill:

1)Establishes the Office of California Drug Safety Watch (Office) in DHS to do all of the following to provide Californians with information on the safety and effectiveness of prescription drugs:

a) Establish a central repository of information about the safety and effectiveness of prescription drugs;

b) Disseminate information to health care professionals and consumers through an Internet Web site which shall include links to other relevant web-based information that has been professionally reviewed and approved;

c) Assure that the dissemination of information is done in a culturally competent manner;

d) In selecting therapeutic classes of drugs about which to develop information, give priority to therapeutic classes that have one or all of the following characteristics:

i) Classes of drugs in which there have been recently published reports of safety concerns;

ii) Classes of drugs that have been advertised on television directly to consumers; and,

iii) Classes of drugs for which there is recently published systematically reviewed evidence-based research.

e) Request units of the University of California and the California State University to provide assistance; and,

f) Rely on systematically reviewed evidence-based research.

2)Authorizes the Office to review the formularies of all state-funded programs for their utilization of systematically reviewed evidence-based research.

3)Coordinates its activities with other state departments and agencies to avoid unnecessary duplication.

4)Defines the following:

a) Evidence-based research means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups; and,

b) Systematically reviewed means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of healthcare treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.

EXISTING LAW :

1)Regulates the packaging, labeling and advertising of food, drugs, and cosmetics under the administration of DHS.

2)Creates in the federal government the Food and Drug Administration (FDA) to regulate prescription drugs.

FISCAL EFFECT : Unknown

COMMENTS :

1)PURPOSE OF THIS BILL . To highlight the importance of this bill, the author points to the withdrawal of Vioxx and Celebrex in November and December 2004 from the market because of the risks of heart attack associated with taking these drugs. On April 7, 2005, the FDA asked Pfizer to withdraw Bextra from the market because it increases the risk of heart attacks, stroke and skin reactions. Like Vioxx and Celebrex, Bextra is a cox-2 inhibitor. These events created great insecurities among consumers. The author points out that if there is a single repository of information for the safety and effectiveness of drugs, similar to the information published by Oregon's Drug Effectiveness Review Project (DERP), consumers would have more information on the safety and effectiveness of prescription drugs they are taking and would be encouraged to discuss such information with their physicians. In Oregon, Vioxx was removed from the Medicaid list of preferred drugs based on a DERP review at least two

years before the manufacturer decided to pull the drug out of the market.

2)DRUG EFFECTIVENESS REVIEW PROJECT (DERP) . This bill allows the Internet Website that this bill establishes to be linked to other web-based information that has been professionally reviewed and approved, such as DERP. DERP is a collaboration designed to obtain the best available evidence-based research in comparing the effectiveness and safety of drugs in the same class. The source of evidence is a series of comprehensive, updated and unbiased systematic reviews conducted by Evidence Based Practice Centers (EPC) with oversight and coordination from the Oregon EPC. It makes available information regarding the comparative effectiveness and safety profiles of different drugs within pharmaceutical classes. Its reports are not usage guidelines, nor an endorsement of, or recommendation for, any particular drug, use or approach. It is a three-year, $4.2 million undertaking among its 12 member states, namely Alaska, Arkansas, Idaho, Kansas, Minnesota, Missouri, Montana, North Carolina, Oregon, Washington, Wisconsin and Wyoming. California's Department of Health Services, CalPERS and the California Healthcare Foundation also participate. DERP already reviewed 15 classes of drugs which include cox-2 inhibitors and anti-cholesterol statins, like Crestor. According to news reports, as early as 2002, DERP's reports raised safety concerns about Vioxx and two of its member states, Oregon and Washington, used the independent analysis to remove Vioxx from its preferred drugs that doctors use when prescribing medication for Medicaid recipients.

3)WEBSITES . Recently, the AARP and Consumers Union (CU) developed and established their own Internet Web sites to serve as an online guide for specific prescription drugs. In 2004, CU launched www.CRBestBuyDrugs.com to compare a variety of prescription drugs on price, effectiveness and safety to help consumers and doctors identify the most effective and affordable medicines. CU's published drug reports include beta-blockers, anti-depressants, statins, proton pump inhibitors (for heartburn and acid reflux) and non-steroidal anti-inflammatory drugs (NSAIDs) for arthritis and pain. Drug price information used in the CU reports is based on average retail prices paid in cash by consumers at the pharmacy and the reports are peer-reviewed by medical experts in the particular drug category. CU uses the evidence-based research reports of DERP as a basis for its reports. AARP, through its website, publishes conclusions about the effectiveness and safety of specific drugs. AARP also bases its conclusions on the effectiveness and safety of drugs from DERP reports. AARP's website states that its intended purpose is to inform, and not limit consumer choices. Among the drugs with published reviews on AARP's website are Crestor, Celebrex, Bextra, Lipitor and Nexium.

4)CONSUMER PERCEPTION . The pull-out of Vioxx and Celebrex and most recently Bextra from the market because of adverse drug reactions has changed the landscape on how consumers view drugs and associated risks. A 2005 Kaiser Family Foundation survey found that 66% of adults closely followed news stories about Vioxx and Celebrex in December 2004 and a large majority (80%) felt "somewhat" confident about the safety of prescription drugs sold in the United States. The same survey indicated that a vast majority of adults (90%) have seen or heard advertisements for prescription drugs but only 18% of consumers now believe pharmaceutical ads can be trusted "most of the time." This is a significant drop because in 1997 one-third of those surveyed indicated ads could be trusted most of the time. The importance of these drug advertisements to delivering the safety or risks of drugs has caught the attention of the FDA when it announced that it would be more aggressive in monitoring drug advertisements so as to balance the presentation of the benefits and risks of particular drugs.

5)EVIDENCE-BASED RESEARCH . This bill requires the Office to develop information on classes of drugs for which there is recently published systematically reviewed evidence-based research. Background information provided by the author points out that evidence-based medicine can be a powerful tool for saving money and improving health care. Evidence based medicine can also improve treatment outcomes, increase provider and health plan accountability, and lead to better informed patients and providers.

6)SUPPORT . Supporters indicate that prescription drug safety is a serious concern among Californians. Peer-reviewed and scientifically based studies would provide additional and valuable information to physicians, surgeons and patients. The California Medical Association in support notes the importance of this information while emphasizing the need for patients to consult their physicians before discontinuing any prescribed medications.

7)OPPOSITION . Letters received in opposition appear to address the February 11, 2005 version of this bill, which would have required DHS to establish a toll-free telephone number to receive reports of adverse drug reactions, establish a Web site with adverse drug reaction information, maintain a database and act as a liaison with the FDA. Opponents claim that FDA's Medwatch, which allows reporting of adverse drug reactions, provides sufficient protection to the public. It is unclear whether they are still opposed to this bill in its most recently amended form.

8)RELATED LEGISLATION .

a) AB 1674 (Richman) would require the Department of Managed Health Care to contract with an academic institution or public policy research institution for the establishment of a Center for Quality Medicine to conduct periodic research on various issues related to medical treatment data. AB 1674 has been referred to the Assembly Health Committee.

b) SB 329 (Cedillo) would establish the California Prescription Drug Safety and Effectiveness Commission within the California Health and Human Services Agency to provide Californians with information on the safety and effectiveness of prescription drugs via an Internet Web site. SB 329 has been referred to the Senate Health Committee.

9)PREVIOUS LEGISLATION . AB 2326 (Corbett), of 2004, would have required the Office of Patient Advocate at DMHC to publish a report card before January 1, 2006, and update it annually thereafter, on the safety, effectiveness, and cost of prescription drugs, to be posted on DMHC's Internet Web site. This bill failed passage in the Senate Appropriations Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

Senior Action Network (sponsor)
AIDS Healthcare Foundation
California Alliance for Retired Americans
*
California Chiropractic Association *
California Labor Federation *
California Medical Association
California Public Interest Research Group *
*
California School Employees Association *
Consumers Union *
Gray Panthers *
Health Access *
Older Women's League *
Retired Public Employees Association *
Service Employees International Union

Opposition

C
alifornia Healthcare Institute *
Novartis *
Pharmaceutical Research and Manufacturers of America *
Wyeth *

* prior version

Analysis Prepared by: Rosielyn Pulmano / HEALTH / (916) 319-2097

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AMENDED IN SENATE APRIL 11, 2005

SENATE BILL No. 380

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report *all suspected* serious adverse drug events that ~~they observe~~ *are spontaneously discovered or observed in medical practice* to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. *The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law.*

~~By changing the definition of a crime, this bill would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~yes~~ *no*. State-mandated local program: ~~yes~~ *no*.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The federal Food and Drug Administration (FDA) operates a voluntary reporting system for adverse drug reactions known as the MedWatch system.

(b) The FDA currently estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA.

(c) Given the prevalence of pharmaceuticals and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market due to safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

(d) Requiring licensed health professionals of organizations to report adverse drug events to the FDA would increase the amount of data available to the FDA about adverse drug reactions, thereby enabling the FDA to discern problems with drugs that arise after they are approved and to take action to protect the public health in a more timely manner.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Adverse Event Reporting

111657. (a) A licensed health professional, including, but not limited to, a physician and surgeon, dentist, or pharmacist, and a health facility, including, but not limited to, a hospital or clinic, shall report *all suspected* serious adverse drug events that ~~they observe~~ *are spontaneously discovered or observed in medical practice* to MedWatch, the drug safety information and adverse

event reporting program operated by the federal Food and Drug Administration.

(b) For purposes of this section, serious adverse drug events shall include adverse health outcomes involving patients that result in death, life–threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

(c) Any health professional or health facility that is required to report an adverse drug event pursuant to this section shall do so using the FDA 3500 Voluntary form developed by the federal Food and Drug Administration for MedWatch.

~~SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

111658. A licensed health professional or health facility that violates any provision of this article shall not be subject to the penalties and remedies outlined in Chapter 8 (commencing with Section 111825).

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 380 **VERSION: AMENDED APRIL 11, 2005**

AUTHOR: ALQUIST **SPONSOR: SENIOR CITIZENS, SO. CAL**

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUGS: ADVERSE EVENT REPORTING

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufactures to report adverse drug reactions.

This Bill:

1) Requires a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

2) Requires the report to be made using FDA 3500, Voluntary form.

3) Defines a serious adverse drug events as, adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

4) Provides that a person or health facility that violates any provision of the measure would not be subject to penalties and remedies in H&S 111825; these penalties are imprisonment for not more than one year in the county jail or a fine of not more than $1,000, or both the imprisonment and fine.

(H&S 111657 Added)

Comment:

1) Author's Intent. The author is concerned that the FDA may not be receiving enough information about adverse drug reactions to make informed decisions to protect the public health.

2) Enforcement. This bill lacks language that would make the bill enforceable. There is no way to know how many adverse drug reactions a health professional observes each year. Consequently this bill would be impossible to enforce. Additionally, it is unclear how each regulatory board would know that an event should have been reported, but wasn't.

3) FDA's MedWatch Program. MedWatch is a voluntary reporting program run by the FDA that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

Reporting is done on line, by phone, or by submitting the MedWatch 3500 form by mail or fax. The FDA disseminates medical product safety alerts, recalls, withdrawals, and important labeling changes to the medical community and the general public via its web site and the Med Watch E-list.

4) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and will be amended for other purposes.

5) History.

2005	
Apr. 11	Read second time. Amended. Re-referred to Com. on APPR.
Apr. 7	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 411.)
Mar. 14	Set for hearing March 30.
Feb. 24	To Com. on HEALTH.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN ASSEMBLY APRIL 4, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 72

Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)

January 3, 2005

~~An act to add Division 114 (commencing with Section 130700) to the Health and Safety Code, relating to prescription drugs.~~ *An act to add Chapter 9 (commencing with Section 119500) to Part 15 of Division 104 of the Health and Safety Code, relating to prescription drug trials.*

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as amended, Frommer. Prescription drugs: ~~manufacturer reporting requirement~~ *clinical trials*.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

~~This bill would require a prescription drug manufacturer that offers for sale, transfers, or otherwise furnishes prescription drugs to any person or entity in this state to submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer pertaining to those drugs. The bill would require the report to be consistent with federal laws applicable to information disseminated by drug manufacturers to a state governmental agency.~~

~~This bill would authorize the Attorney General to bring civil actions to enforce the reporting requirements and recover civil penalties that may be assessed by the Attorney General under the bill.~~

This bill would establish the Patient Safety and Drug Review Transparency Act in order to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. The bill would prohibit an institutional review board with responsibility for ensuring the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs from approving any clinical trial related to a prescription drug unless the sponsor certifies in writing that it (1) will register the clinical trial, no later than 21 days after it begins, with a government sponsored and public clinical trial registry, (2) will publish the results of the study, and (3) has complied with the registry and publication requirements for any prior study that was approved by the board.

This bill would prohibit the board from approving any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board to comply with the above requirements. Prior to approval, the bill would require the board to review whether the sponsor, in prior approved studies, actually complied with those requirements.

The bill would provide that any sponsor who does not comply with the requirements it certified in writing is liable for a civil penalty of $1,000 per violation. The bill would authorize the Attorney General, a district attorney, or city attorney to bring an action against a sponsor to recover civil penalties.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. Division 114 (commencing with Section 130700) is added to the Health and Safety Code, to read:~~

SECTION 1. Chapter 9 (commencing with Section 119500) is added to Part 15 of Division 104 of the Health and Safety Code, to read:

CHAPTER 9. INFORMATION REQUIRED FOR DRUG STUDIES

119500. (a) This chapter may be referred to as the "Patient Safety and Drug Review Transparency Act."

(b) The purpose of this act is to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. Making information about drug trials and their results available in a national, publicly accessible database will improve the safety of human subjects and provide all citizens of this state with complete safety information about the prescription drugs they take.

(c) For purposes of this chapter, the following terms have the following meanings:

(1) "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects and is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

(2) "Clinical trial registry" means a publicly available data bank established by the National Library of Medicine pursuant to 42 U.S.C. Section 282 (j).

(3) "Institutional review board" means an independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well–being of human subjects involved in clinical trials of prescription drugs by, among other things, reviewing, approving, and providing continuing review of trial protocol and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

(4) "Sponsor" means the manufacturer, or if the manufacturer provides no monetary support for the trial, the person who provides the majority of monetary support, or, where the majority funder is a state or federal agency, the principal investigator.

(d) An institutional review board shall not approve any clinical trial related to a prescription drug unless the sponsor certifies in writing that it has done or will do all of the following:

(1) Register the clinical trial, no later than 21 days after it begins, by providing information necessary for publication in a government sponsored and public clinical trial registry in the manner required by regulations or other guidance established by

the National Library of Medicine or the United States Secretary of Health and Human Services.

(2) Publish the results of the study by providing the results of the study for publication in a government sponsored and public clinical trial registry, in a manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services, or in another publicly accessible database.

(3) Complied with the provisions of paragraphs (1) and (2) for any prior study that was approved by the board pursuant to this chapter.

(e) An institutional review board shall not approve any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board pursuant to this chapter to comply with the requirements it certified in writing under subdivision (d). Prior to approval, the board shall review whether the sponsor, in prior studies approved pursuant to this chapter, actually complied with those requirements.

(f) Any sponsor who does not comply with the requirements it certified in writing under subdivision (d) shall be liable for a civil penalty of one thousand dollars ($1,000) per violation payable to the general fund of the entity bringing the action. Each day a sponsor is in violation shall be considered a separate violation. The Attorney General, a district attorney, or city attorney may bring an action against a sponsor to recover civil penalties for not complying with the requirements the sponsor certified in writing under subdivision (d).

~~DIVISION 114. PRESCRIPTION DRUGS~~

~~CHAPTER 1. DRUG MANUFACTURER HEALTH STUDIES REPORTING~~

~~130700. (a) Any manufacturer of prescription drugs that offers for sale, transfers, or otherwise furnishes a prescription drug to any person or entity in this state shall submit a report to the State Department of Health Services of health studies that have been or are being conducted by or on behalf of that manufacturer regarding each prescription drug it sells, transfers, or otherwise furnishes to a person or entity in this state.~~

~~(b) Subject to subdivision (c), the report shall include all studies pertaining to each prescription drug, whether the results are positive, negative, neutral, or inconclusive.~~

~~(c) The report shall be consistent with requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) that apply to the dissemination of information by a drug manufacturer to a state governmental agency.~~

~~130705. (a) The Attorney General may bring a civil action to enforce the requirements of Section 130700.~~

~~(b) (1) The Attorney General may assess and recover a civil penalty, as specified in paragraph (2), against a drug manufacturer for each finding of a violation of Section 130700 in a civil action brought under this section.~~

~~(2) A drug manufacturer that violates Section 130700 is liable for civil penalties of up to twenty-five thousand dollars ($25,000) for each first violation, not less than fifty thousand dollars ($50,000) nor more than one hundred thousand dollars ($100,000) for each second violation, and not less than one hundred fifty thousand dollars ($150,000) nor more than two hundred thousand dollars ($200,000) for each subsequent violation.~~

~~(3) Any civil penalty recovered by the Attorney General under this subdivision shall be deposited in the State Treasury.~~

~~(c) In any action under this section in which judgment is entered against the defendant, the Attorney General shall be awarded reasonable attorney's fees together with the costs of suit.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 72 **VERSION: AMENDED APRIL 4, 2005**

AUTHOR: FROMMER et. al. **SPONSOR: FROMMER**

RECOMMENDED POSITION: NO POSITION

SUBJECT: CLINICAL TRIALS

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establishes the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers to report adverse drug reactions.

This Bill:

1) Establishes the Patient Safety and Drug Review Transparency Act.

2) Defines the terms: "Clinical trial", "Clinical trial registry", "Institutional review board", and "Sponsor."

3) Prohibits an institutional review board from approving any clinical trial related to a prescription drug unless the sponsor certifies in writing that it has done, or will do all of the following:

a. Register the clinical trial, no later than 21 days after it begins, by providing information necessary for publication in a government sponsored and public clinical trial registry.

b. Publish the results of the study by providing the results of the study for publication in a government sponsored and public clinical trial registry, or other publicly accessible database.

c. Complied with the provisions of the measure for any prior study that was approved by the board.

4) Prohibits an institutional review board from approving any clinical trial related to a prescription drug if the sponsor failed, during a prior study that was approved by the board pursuant to this measure, to publish the results of clinical trial studies.

5) Establishes a civil penalty of $1,000 per violation for any sponsor who does not comply with the requirements it certified in writing. Each day a sponsor is in violation would be considered a separate violation.

(H&S 119500 Added)

Comment:

1) Author's Intent. The author's intent is to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

2) Amended on April 4, 2005. This bill was gutted and amended on April 4, 2005. The previous version of this bill required a manufacturer of prescription drugs that offers for sale, transfers, or furnishes a prescription drug to any person or entity in this state, to submit a report to the Department of Health Services (DHS) of health studies that have been or are being conducted for each prescription drug it sells, transfers, or furnishes in this state.

3) History.

2005	
Apr. 5	Re-referred to Com. on HEALTH.
Apr. 4	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and JUD.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

BILL ANALYSIS
AB 72

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 72 (Frommer) - As Amended: April 4, 2005

SUBJECT : Prescription drugs: clinical trials.

SUMMARY : Prohibits an institutional review board (IRB) from approving prescription drug clinical trials unless the trial has been registered and the results will be published, as specified. Specifically, this bill :

1)Prohibits an IRB from approving any clinical trial related to a prescription drug unless the sponsor certifies in writing that it has done or will do all of the following:

a) Register the clinical trial, no later than 21 days after it begins, by providing information necessary for publication in a government sponsored and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the U.S. Department of Health and Human Services (HHS);

b) Publish the results of the study by providing the results of the study for publication in a government sponsored and public clinical trial registry, in a manner required by regulations or other guidance established by the National Library of Medicine or the HHS, or in another publicly accessible database; and,

c) Comply with the provisions of a) and b), above, for any prior study that was approved by the IRB pursuant to this bill.

2)Requires an IRB, prior to approving a clinical trial, to review whether the sponsor complied with the requirements of this bill, in prior approved trials. Prohibits an IRB from approving any study related to a prescription drug if the sponsor failed during a prior study that was approved by the IRB pursuant to this bill to comply with the requirements it certified in writing under #1) above.

3)Makes any sponsor who does not comply with the requirements it certified in writing under #1) above liable for a civil penalty of $1,000 per violation.

4)Defines, for the purpose of this bill, the following terms: clinical trial, clinical trial registry, institutional review board, and sponsor.

EXISTING LAW :

1)Defines, under federal regulations, an IRB as an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. Authorizes an IRB to approve, require modifications in (to secure approval), or disapprove research.

2)Requires, under federal law, the Secretary of HHS to establish a publicly accessible data bank of information about clinical trials for serious or life threatening diseases and conditions. Requires the sponsors of investigational new drug applications to submit to the data bank a description of the purpose of each experimental drug, eligibility criteria for participation in the trial, the location of clinical trial sites and a point of contact for people interested in enrolling in the trial.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill would improve the safety of prescription drugs by ensuring that patients, physicians, and researchers could access information about the clinical trials that test the safety and effectiveness of those drugs. The author states that federal law dealing with clinical trials fails to require registration of all trials, does not penalize companies that fail to register their trials and does not mandate the publication of the results of these trials. The author believes that this bill will not only improve patient care, but could also reduce health care costs. According to the author, research has shown that publication bias (that is, that studies showing positive results are more likely to be published than studies showing negative results) leads to a bias toward new and more expensive treatment options. A clinical trial registry can help patients and doctors understand that in some cases less expensive treatment may be just as effective. Although federal legislation has been introduced to address some of these shortcomings, the author states that Congress shows little willingness to ensure that the public gets the information it needs about clinical trials. As a result, states must step in with legislation such as this bill.

2)BACKGROUND . Current state law does not require the registration of a clinical trial or the publication of the

results of a trial. Congress, in the Food and Drug Administration Modernization Act (FDAMA) of 1997, required HHS to establish a publicly accessible data bank of information about clinical trials for serious or life threatening diseases and conditions. FDAMA also requires the sponsors of investigational new drug applications to submit to the data bank a description of the purpose of each experimental drug, eligibility criteria for participation in the trial, the location of clinical trial sites and a point of contact for people interested in enrolling in the trial.

To implement this law, the National Institutes of Health, through its National Library of Medicine, and the FDA developed the ClinicalTrials.gov website in 2000 to serve as the data bank for clinical trial information. Despite the best efforts by the FDA to inform drug manufacturers and drug trial sponsors of the FDAMA registration requirements, an FDA review published in 2004 found that:

a) Some pharmaceutical companies are not providing adequate information about their trials, for example, some trials are listed without identifying the sponsoring company or the drug being tested;
b) Some companies listed no trials and some listed only a few that follow FDA guidelines;
c) Only 48% of mandated industry-sponsored and 91% of mandated NIH cancer-related trials were registered; and,
d) For non-cancer trials, participation appeared to be in the single-digit range for some serious disease categories.

In June 2004, the American Medical Association (AMA) recommended that HHS create a comprehensive, centralized clinical trials registry. The AMA further called on all IRBs to make registration in this database a condition of their approval of the bioethical aspects of clinical trials. An AMA trustee testified before Congress that "physicians need complete and unbiased information about the drugs they prescribe for their patients, and that physicians need complete and unbiased information about the safety and effectiveness of the treatments they prescribe for their patients. A centralized clinical trials registry would improve physician and researcher access to this information."

In 2004 the International Committee of Medical Journal Editors (ICMJE) published an editorial in the New England Journal of Medicine stating that ICMJE member journals will require, as a condition of consideration for publication, registration of the clinical trials being reported on in a public trials registry such as ClinicalTrials.gov, effective for any trial starting enrollment after July 1, 2005. The editors noted

that selective reporting of trials distorts the evidence available for clinical decision-making, and that trial results that place financial interests at risk are particularly likely to remain unpublished and hidden from public view. In addition the editors stated: "When research sponsors or investigators conceal the presence of selected trials, these studies cannot influence the thinking of patients, clinicians, other researchers and experts who write practice guidelines or decide on insurance-coverage policy. If all trials are registered in a public repository at their inception, every trial's existence is part of the public record and the many stakeholders in clinical research can explore the full range of clinical evidence."

The Congressional Research Service reports that the pharmaceutical industry's reaction to clinical trials reporting has been mixed, although as litigation and FDA and congressional interest have increased, some individual manufacturers and groups have volunteered to make some of their clinical trials data public. In a January 2005 story, the Boston Globe reported that six months after the industry vowed to make its clinical trials more transparent, and three months after launching a common website to give the public "unprecedented access" to studies both good and bad, drug companies have posted unpublished trial results on the site for just five drugs.

3)SUPPORT . Supporters argue that this bill is necessary in order to protect the public from possible adverse side effects of prescription drugs. Supporters believe that the more information provided by the manufacturer concerning the trials, the better informed the public will be about the uses and effects of the drug. One supporter, a clinical pharmacy professor, states that when members of the public agree to participate in trial, it is on the understanding that they are contributing to the global body of health-related knowledge and that it is unethical to conduct human research without ensuring that reliable descriptions of the study and its findings are publicly available.

4)OPPOSITION . (prior version) Opponents argue that this bill is unnecessary for at least two reasons. First, under current federal law, manufacturers are required to post on a government website clinical trials that deal with serious or life-threatening diseases. Second, beginning July 1, 2005, Pharmaceutical Research and Manufacturers of America (PhRMA), will post, on a voluntary basis, information about all new mid to late stage clinical trials. Opponents claim that with this new policy, doctors and patients will now have unprecedented access to current and ongoing clinical trials.

5)RELATED FEDERAL LEGISLATION . On February 28, 2005, Senators Dodd, Grassley, Johnson, and Wyden introduced legislation in Congress to require pharmaceutical and medical device companies to report the results of all clinical trials on a public, electronic database.

6)DOUBLE REFERRAL . This bill, as introduced, was double-referred to the Assembly Judiciary Committee. With the amendments of April 4, 2005, this bill may no longer be in the jurisdiction of the Judiciary Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

AIDS Healthcare Foundation*
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Chiropractic Association
California Federation of Teachers
California Labor Federation
California Public Interest Research Group (CalPIRG)*
California School Employees Association
Consumers Union
Health Access California
Retired Public Employees Association*
Service Employees International Union*
One clinical pharmacy professor*

(*current version)

Opposition

California Healthcare Institute
Pharmaceutical Research and Manufacturers of America
Wyeth Pharmaceuticals

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

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AMENDED IN ASSEMBLY MARCH 17, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 73

Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members *Baca,* Bass, *Berg, Coto, De La Torre,* Evans, *Goldberg,* Gordon, *Hancock, Klehs,* Koretz, *Leno, Levine,* Nava, Pavley~~, and Salinas~~, *Ridley-Thomas, Ruskin, Salinas, and Torrico*)

January 3, 2005

An act to ~~add Section 14982 to the Government Code, and to~~ add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 73, as amended, Frommer. Prescription drugs: importation: procurement.

~~(1)~~ Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation,

compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would establish the California Rx Prescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program and establish a Web site on or before July 1, 2006, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical programs, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland and that meet specified requirements, and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site.

~~(2) Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.~~

~~This bill would require the department to coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements to be listed on the California Rx Prescription Drug Web site. The bill would require the department, on or before January 1, 2007, to conduct the review and report to the Legislature. The bill would require the report to~~

~~recommend options to facilitate more cost-effective acquisition of prescription drugs. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs from international pharmacies would be made at reduced prices for purposes of state departments and agencies.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) The United States is the largest trade market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand name pharmaceuticals in the world.

(c) Increased spending on prescription drugs is a significant driver of increases in overall health care costs, with spending nationwide on prescription drugs rising over 15 percent each year from 2000 to 2002.

(d) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as evidenced by federal government statistics *that* show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(e) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that year.

(f) The rising cost of prescription drugs also places a significant burden on state government, with the cost of providing prescription drugs to Medi-Cal beneficiaries, to inmates of the Department of Corrections, and to other participants in state programs growing in some cases at over 20 percent annually in recent years.

(g) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford

the medication they need to stay healthy, as shown by a study by the RAND Corporation that found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20 percent and subsequently experienced higher rates of emergency room visits and hospital stays.

(h) The rising cost of prescription drugs places a disproportionate burden on communities of color, as shown in a report from the Center for Studying Health System Change that found that African-Americans are about 75 percent and Latinos about 50 percent more likely than nonminorities to not have purchased a prescription drug in 2001 because of cost issues.

(i) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(j) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

~~SEC. 2. Section 14982 is added to the Government Code, to read:~~

~~14982. (a) The Department of General Services shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from sources other than those from which the state now purchases, including sources that meet the requirements of Section 110242 of the Health and Safety Code. State departments to be reviewed shall include, but not be limited to, all of the following:~~

~~(1) The State Department of Health Services.~~

~~(2) The Managed Risk Medical Insurance Board.~~

~~(3) The Department of General Services.~~

~~(4) The Department of Corrections.~~

~~(5) The California Public Employees' Retirement System (CalPERS).~~

~~(b) The Department of General Services shall, on or before January 1, 2007, conduct the review required under subdivision (a) and report its findings based on that review to the Legislature. The report shall recommend options to the Legislature, including conducting pilot programs, to facilitate more cost-effective acquisition of prescription drugs. The recommendations shall~~

~~include a determination of the need to seek any federal approvals or waivers.~~

~~(c) The Department of General Services may establish pilot programs under which purchases of prescription drugs from international pharmacies are made at reduced prices for purposes of state departments and agencies.~~

~~(d) As a condition of implementing any pilot program under this section, the Department of General Services shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.~~

~~SEC. 3.~~

SEC. 2. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Prescription Drug Web Site Program

110242. (a) The California Rx Prescription Drug Web Site Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2006, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(4) International pharmacies that provide mail-order service to the United States and who meet the requirements of paragraph (2) of subdivision (d).

(5) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs

at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(d) (1) The Web site shall include price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).

(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, ~~England~~ *the United Kingdom*, and Ireland that provide mail-order services to the United States and that meet all of the following requirements:

(A) Are licensed by the province or country, as appropriate, in which they are located.

(B) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, except that for purposes of this section all references to "state" in subdivision (d) of Section 4112 of the Business and Professions Code shall be deemed to refer to the province or other licensing jurisdiction in which the pharmacy is located. Compliance with this subparagraph shall be determined by the department in consultation with the California State Board of Pharmacy.

(C) Require a prescription from a patient's personal physician, who is licensed to practice in the United States.

(D) Require the completion of a relevant medical history profile.

(E) Require a signed patient agreement.

(F) Ship prescription drugs in tamperproof original manufacturer containers to individuals in the United States, unless the consumer requests to receive the drug in a childproof container.

(G) Include a physical address and pharmacy license number on its company Web site.

(H) Do not furnish any of the following:

(i) A controlled substance.

(ii) A biological product, as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(iii) An infused drug, including, a peritoneal dialysis solution.

(iv) An intravenously injected drug.

(v) A drug that is inhaled during surgery.

(vi) A drug that requires refrigeration or cannot be safely shipped by mail.

(vii) More than the prescribed amount of a drug or more than a three-month supply of any drug.

(viii) A drug that the consumer indicates he or she has not previously taken.

(ix) A drug for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.

(I) Sell only prescription drugs that have been approved for sale in the country in which the pharmacy is located by the agency responsible for ensuring the safety of prescription drugs in that country.

(J) Comply with state law regarding the documentation of the pedigree of prescription drugs.

(K) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.

(L) Maintain a service department to respond to consumer inquiries and provide information to consumers about how they may file complaints with the provincial or other applicable licensing authority.

(M) Ensure that all physicians, pharmacists, and technicians in its employ are properly licensed and their licenses are in good standing.

(N) Comply with all personal health and medical information privacy laws applicable to pharmacies located in California.

(O) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription drugs.

(3) A pharmacy that seeks to be linked to the department's Web site pursuant to paragraph (2) shall apply to the department. The department may enter into a contract with a pharmacy that it determines meets the requirements of paragraph (2). A contract may be renewed annually upon payment of the fee specified in paragraph (5) provided that the pharmacy continues to comply with the requirements of paragraph (2).

(4) The department may terminate a contract with, and delete an electronic link to, or information about, a pharmacy that the

department determines no longer complies with the requirements of paragraph (2). The department shall review within 30 business days any information that it receives regarding a pharmacy's compliance with the requirements of paragraph (2) and shall determine whether the information constitutes grounds for removal of the pharmacy from the Web site.

(5) The department may assess a fee on international pharmacies that the department reviews pursuant to paragraph (2) to offset the cost of reviewing those pharmacies.

(e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

(f) Any information, including the identity of an international pharmacy, to be posted on the Web site shall first be approved by professional staff of the department before it is posted.

(g) The department shall include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. The notice shall also inform consumers that a pharmacy linked to the Web site is licensed in the country in which it is located and that the department has the right to remove a pharmacy from the Web site if it violates the requirements of paragraph (2) of subdivision (d) or the terms of any agreement between the department and the pharmacy. In addition, the notice shall include a statement that the state accepts no legal liability with respect to any product offered or pharmaceutical services provided by a pharmacy linked to the Web site.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 73 **VERSION: AS AMENDED MARCH 17, 2005**

AUTHOR: FROMMER et al. **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUG IMPORTATION

Existing Law:

1) Requires non-resident pharmacies to be licensed by the board. (B&P 4112)

2) Prohibits the importation of prescription drugs except by a drug manufacturer. (21CFR 381)

This Bill:

1) Makes a number of legislative findings about the costs and necessity of prescription drugs.

2) Requires the Department of Health Services (DHS) to establish a Web site on or before July 1, 2006 that will provide consumers with information on how to purchase prescription drugs more affordably. The Web site would include the following information:

a. The availability of a prescription drug benefit through Medicare, including the Voluntary Prescription Drug Benefit.
b. Discount drug programs available through the state.
c. Discount drug programs operated by drug manufacturers.
d. Canadian pharmacies that are approved by the department.
e. International pharmacies (Canada, England, and Ireland) that provide mail order service to the Untied States and contract with the department.
f. Links to any other Web sites deemed appropriate by the department.

(H&S 110242 Added)

3) Requires the Web site to include price comparisons between typical pharmacy prices and international pharmacy prices for the 50 most commonly prescribed drugs.

(H&S 110242 Added)

4) Establishes the requirements that must be met for DHSt to "certify" a pharmacy located in Canada, England, or Ireland to include:

a. Verification of licensure by the appropriate province or country.
b. Compliance with the requirements that must be met by non-resident pharmacies. This determination will be made in consultation with the board.
c. Requires a prescription from the patient's personal physician.
d. Requires a patient medical history.
e. Requires a signed patient agreement.

f. Requires prescriptions to be mailed in original packaging.
g. Requires physical address and phone number for the pharmacy on the pharmacy Web site.
h. Prohibits the pharmacy from furnishing the following drugs:
    i. Controlled substances.
    ii. Biologics.
    iii. Infused drugs.
    iv. Intravenous drugs.
    v. Drugs inhaled during surgery.
    vi. Drugs requiring refrigeration or that are otherwise inappropriate for mail delivery.
i. Sale of only drugs approved by the country in which the pharmacy is located.
j. Comply with California law relating to drug pedigree.
k. Prohibits requiring patients to sign a waiver of liability.
l. Requires the pharmacy to maintain a customer service department.
m. Requires the pharmacy to employ professionals that are licensed in good standing.
n. Requires the pharmacy to comply with California privacy laws.
o. Prohibits filling a prescription if the patient hasn't taken the drug previously.
p. Prohibits furnishing drugs that have no equivalent approved by the FDA.

(H&S 110242 Added)

5) Permits the department to remove approved pharmacies from the Web site if the pharmacy fails to meet any of the above listed requirements. (H&S 110242 Added)

6) Permits the department to assess a fee on international pharmacies to fund this act. (H&S 110242 Added)

Comment:

1) Author's Intent. The author's intent is to provide relief for Californians who are "fed up with sky-high pharmaceutical drug prices and concerned about the safety of those drugs." AB 73 is part of an eight-bill package being offered by Assembly Democrats to bring down the cost of prescription drugs sold in California.

2) Importation. Existing federal law generally restricts the importation of prescription drugs to drug manufacturers. Federal law can permit the importation of prescription drugs by drug wholesalers and pharmacies if the Secretary of Health and Human Services (Secretary) issues a finding that such a practice would be safe. Such a finding has not been issued by the Secretary.

The Food and Drug Administration (FDA) has for many years allowed individuals to purchase drugs abroad in limited amounts and bring them into the United States for personal use. Recent statements by FDA officials have reinforced that the FDA does not intend to prosecute individuals who import drugs for their own use. However, the FDA has taken legal action against some storefronts that assist consumers in ordering drugs from Canadian pharmacies at lower prices. The FDA has also taken legal action against entities that serve as middlemen between Canadian drug suppliers and those state and local governments that have sought to purchase Canadian drugs for their beneficiaries.

3) Price Controls. Consumers seek to purchase drugs from Canadian and EC pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. ***Branded*** drugs can commonly be purchased from Canadian

pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board has been sympathetic to the difficulty of those without drug insurance have to obtain the drugs they need.

Much of the public debate regarding the importation of drugs from Canada has focused on the safety of imported drugs. Consumers are seeking Canadian and EC drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies.

5) Federal Legislation. Three bills have been introduced in Congress that would amend the Federal Food, Drug, and Cosmetic Act to permit the importation of prescription drugs from outside the United States. The bills place limits on the types of drugs that could be imported and from which countries the importation can take place. The bills are S 334, HR 328 and HR 700; none of the bills has yet to be heard in committee.

6) Other States. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

7) State Legislation. AB 1957 (Frommer et.al. 2004), Drug Importation, was introduced last session, AB 73 is similar to AB 1957 except AB 73 expands the list of countries for drug importation to include England and Ireland, or any other country. The board opposed AB 1957 and the Governor vetoed the measure. In the Governor's veto message he states "...importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability.... In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians."

8) Support & Opposition.

Support:

AIDS Healthcare Foundation
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Medical Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
City Council and City of Compton
Consumers Union
County of San Joaquin
Health Access California
Lieutenant Governor Cruz Bustamante
NAMI California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Oppose:

BIOCOM
California Chamber of Commerce
California Health Institute
Pharmaceutical Research and Manufacturers of America

9) History.

2005

Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 10. Noes 4.) (April 12).
Mar. 29	Re-referred to Com. on HEALTH.
Mar. 17	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

BILL ANALYSIS
AB 73

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 73 (Frommer) - As Amended: March 17, 2005

SUBJECT : Prescription drugs: importation: procurement.

SUMMARY : Requires the Department of Health Services (DHS) to establish a Web site to facilitate purchasing prescription drugs at reduced prices. Requires the Web site to include price comparisons, including prices of, and links to, international pharmacies that meet specified requirements. Specifically, this bill :

1)Establishes the California Rx Prescription Drug Web Site Program, administered by DHS, to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

2)Requires DHS to establish a Web site on or before July 1, 2006, to provide at a minimum information about, and electronic links to, all of the following:

a) Prescription drug benefits available to Medicare beneficiaries;

b) State programs that provide drugs at discounted prices for California residents;

c) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals;

d) Pharmacies in Canada, the United Kingdom, and Ireland that provide mail-order service to the United States and which meet specified requirements to assure safety, accessibility, and affordability of prescription drugs; and,

e) Other Web sites as deemed appropriate by DHS.

3)Requires the Web site to include price comparisons of at least 50 commonly prescribed brand name prescription drugs, as specified.

4)Permits DHS to enter into a contract with an international pharmacy that meets requirements specified in this bill.

Permits DHS to terminate a contract with, and delete an electronic link to, or information about, an international pharmacy that no longer complies with the requirements of this bill.

5)Requires a contracted international pharmacy to be licensed by the province or country in which it is located and to comply with the requirements of a nonresident pharmacy, as specified.

6)Permits DHS to assess a fee on international pharmacies to offset the cost of reviewing applications of those pharmacies.

7)Requires DHS to ensure that the Web site required by this bill is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs. Requires that any information posted on the Web site first be approved by DHS professional staff.

8)Requires DHS to include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. Requires other specified notices.

EXISTING LAW :

1)Provides that any pharmacy located outside of California that delivers prescription drugs into the state is considered a nonresident pharmacy. Requires a nonresident pharmacy to register with the Board of Pharmacy and comply with all lawful directions of and requests for information from the state in which it is a resident.

2)Prohibits, under the federal law, the importation or reimportation of prescription drugs except by the original manufacturer.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill provides relief from the high costs consumers are paying for prescription drugs. These high prices are hurting many Californians, including one-quarter of seniors who skip doses or fail to get medications because of cost. The author reports that the high cost of drugs has a disproportionate effect on African-Americans, who are 75% more likely than whites not to have bought a prescription drug because of cost. Latinos are 50% more likely than whites not to have bought drugs because they cannot afford them. As a result of these

high costs, the author notes that many consumers are turning to Canada and other countries, where brand-name drugs can be 30 to 75 % cheaper than in the United States. According to the author, this bill would enable the state of California to provide a valuable service to its residents by giving them information about safe, reputable mail-order pharmacies located in Canada, the UK and Ireland.

2)BACKGROUND . Spending on prescription drugs grew at a real (inflation-adjusted) average annual rate of 14.5% from 1997 to 2002. That rapid growth raised prescription drug spending's share of total health expenditures to 11% in 2003, compared with 5.8% a decade earlier. In 2003, American consumers paid $53.2 billion in out-of-pocket costs for prescription drugs, an increase of 26% over 2001.

Californians without drug coverage have been especially hard hit. Some must choose between food, rent, and needed medications. A 2003 Kaiser Family Foundation survey found that 37% of the uninsured, when they finally did see a doctor, did not fill a needed prescription because of cost. Even those with drug coverage, especially through Medicare HMOs and Medicare Supplement policies, find the cost of prescription drugs often far exceeds their coverage limits. Other insured Californians are hit with 3-tiered drug benefits, increased cost-sharing and decreased access to needed drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20% and experienced higher rates of emergency room visits and hospital stays. The Medicare Prescription Drug and Modernization Act of 2003 (MMA) will provide some relief to seniors when it takes effect on January 1, 2006. Even then many seniors will be responsible for significant out-of-pocket expenses. For instance, a senior with $5100 in drug spending will be responsible for $3600 of that amount in addition to an annual premium of at least $420.

The ever-increasing cost of prescription drugs has forced growing numbers of Americans, many of them elderly citizens living on fixed incomes, to buy essential medications from beyond U.S. borders. Each year, millions of Americans achieve some level of financial relief by purchasing prescription drugs from Canada, Mexico, Europe, and Southeast Asia. The recent development of Canadian Internet pharmacies has demonstrated the true demand for inexpensive medication. Researchers estimate that over six million Americans have obtained needed medicines from online Canadian pharmacies. The federal government estimates that consumer spending on drugs from Canada and other countries totaled $1.1 billion in 2003.

3)SAFETY CONCERNS . It is generally agreed that the Canadian regulatory systems for approving and distributing drugs is very similar to that in the US. In the US, the approval and marketing of prescription drugs is governed under the Federal Food, Drug, and Cosmetic Act, with enforcement administered by the Food and Drug Administration (FDA). In Canada, the approval and marketing practices are regulated under the Food and Drugs Act, with enforcement by the Therapeutic Products Directorate, an arm of Health Canada, which is responsible for assuring the safety and quality of all medicines sold in Canada. Both countries' statutes require drugs to be proven safe and effective through clinical studies and manufactured to strict quality standards before they can be approved and distributed for general use. In addition, both countries have analogous requirements for licensing of retail pharmacies and pharmacists; in Canada, licensing is conducted by provinces or territories, whereas in the U.S. it is done by states.

Studies by two federal agencies, the Congressional Research Service (CRS) and the Government Accountability Office, report that the drug distribution system in Canada is as safe as or safer than our own. The CRS study, for example, shows that Health Canada regulates the drug supply system in Canada in ways that make drug distribution there safer than in the U.S. because drugs pass through the hands of fewer middlemen, reducing the opportunity for counterfeit drugs to enter the supply chain. In June 2004, the GAO issued a report that found that Canadian internet pharmacies had safer pharmacy practices than American internet pharmacies. All of the Canadian pharmacies examined by the GAO required a prescription, for example, while only one in six American internet pharmacies did so. In contrast, a U.S. Department of Health and Human Services report, mandated by the MMA and released in December 2004, recommended against legalizing personal importation, after concluding it would result in significant safety risks, decreased research and development, liability issues and small national savings. The conclusions of the study were severely critiqued by proponents of importation as having been preordained.

4)FEDERAL LAW . Federal law allows only the manufacturer to import, or reimport, prescription drugs into the U.S. However, the FDA and U.S. Customs, because of their enforcement discretion and finite resources, have not enforced the importation ban on individuals bringing limited supplies of drugs for personal use across the border. Prescription drugs sent to American consumers through the mail also appear to enjoy the benefit of this enforcement discretion. Attempts to legalize importation at the federal level have been unsuccessful thus far. In each of the past 5 years a number measures to allow importation from Canada and other countries

have been introduced in both houses of Congress without success.

5)LIABILITY ISSUES . The author has received a formal opinion from Legislative Counsel regarding liability issues. Legislative Counsel has concluded that the state could be subject to liability for negligence under state law in limited circumstances, such as negligent ministerial errors committed by the Board or its employees (as in listing an incorrect pharmacy on the web site), unless the Legislature enacts a statute providing immunity from liability to cover those activities and the Board includes on its web site adequate notice and disclaimers regarding applicable federal law. Most of the activities of the Board and its employees in establishing and maintaining the web site would be considered discretionary, rather than ministerial, acts; the state is immune from liability for errors in discretionary acts under the California Tort Claims Act. An example of a potential ministerial error related to this bill would be the listing of an unapproved pharmacy in the place of an approved one on the website, or listing an approved pharmacy at the Internet address of an unapproved pharmacy, where the error resulted in the purchase of a drug that caused harm. A discretionary act would include deciding which Canadian pharmacies meet the standards this bill requires. The state would not be liable for making that decision in error because the decision making is a discretionary act.

6)CANADIAN SUPPLY ISSUES . In response to pressure from the Bush Administration, late in 2004 the Health Minister of Canada reversed his previous position that existing levels of sales to Americans posed no threat to the drug supply of Canada. Instead, the Health Minister and the Canadian government have begun to discuss the possibility of shutting down mail-order pharmacies. Although no action has been taken to date, in light of this threat to the supply of drugs sold to Americans, and in response to continuing efforts by drug manufacturers to restrict the supply of drugs into Canada, a number of states have examined whether their programs should link consumers to pharmacies in other countries besides Canada.

In the past year, representatives of the state of Illinois and of the state of Minnesota made separate visits to Europe to assess the quality of European pharmacies and pharmacists. Findings from these visits included: European pharmacist training is substantially equivalent to the US; pharmacy storage rules are similar; European distribution systems are similar to Canada (closed system with fewer opportunities for counterfeit drugs than in the U.S.); and European drug dispensing is safer and less prone to error (drugs are dispensed in manufacturer's precounted blister packs). In

October 2004, after receiving the results of his state's research on European importation, Illinois Governor Blagojevich launched the I-SaveRx program to provide access to Canadian, British and Irish pharmacies. Initially the program was open only to residents of Illinois and Wisconsin, but in recent months the states of Missouri, Kansas and Vermont have also joined. Minnesota Governor Pawlenty has yet to decide whether to expand the Minnesota RxConnect program, which links to Canada, to include European pharmacies.

Despite some narrowing of price differentials between the United States and Canada in the past year due to the weakening American dollar, consumers can still find substantial savings purchasing drugs from Canadian or British pharmacies. The author's office reports that a survey of prices of nine commonly prescribed medications listed on pharmacychecker.com on April 1, 2005, comparing costco.com prices with those available at Canadian and British pharmacies, revealed savings on a per pill basis of from 24 to 65% from the Canadian or British pharmacies.

7)SUPPORT . The California Medical Association, in support, argues that many patients are unable to follow a prescribed drug regime due to the high cost of prescription drugs and need the options this bill will provide. Other supporters argue that Californians are overburdened by overpriced drugs and need information on affordable and safe domestic and international sources of drugs. Supporters also argue that Democratic and Republican governors in other states have established websites for their residents to buy affordable drugs safely from other countries and that the time has come for California to join this nationwide effort.

8)OPPOSITION . Opponents argue that this bill puts consumer safety at risk, raises state liability concerns, and has a negative impact on biomedical research. The Pharmaceutical Research and Manufacturers of America (PhRMA) also argues that there are better and readily available programs to enable patients to access safe and affordable medicines. These include existing patient assistance programs which provided medicine to 244,000 Californians in 2002, a recently launched industry sponsored website, rxhelpforca.org, and the new Medicare prescription drug benefit that will go into full effect on January 1, 2006.

9)PREVIOUS LEGISLATION . AB 1957 (Frommer) of 2004, would have required DHS to establish a Web site to facilitate purchasing prescription drugs at reduced prices with links to Canadian pharmacies. SB 1149 (Ortiz) of 2004 would have required the Board of Pharmacy to establish a Web site to facilitate purchasing prescription drugs at reduced prices and would also

have included links to Canadian pharmacies. SB 1333 (Perata) of 2004 would have permitted DHS to reimburse pharmacies for drugs dispensed to Medi-Cal and AIDS Drug Assistance Program beneficiaries that are purchased from a Canadian pharmacy. AB 1957, SB 1149, and SB 1333 were all vetoed by the Governor, who stated that importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. However, in a formal legal opinion dated April 1, 2005, Legislative Counsel opined that the federal Food, Drug and Cosmetic Act would not have preempted the provisions of AB 1957 that would have established a prescription drug website with Canadian links.

10)RELATED LEGISLATION . AB 74 (Gordon) establishes the California Rx Prescription Drug Hotline to provide information about affordable prescription drug prices using a low-cost 1-900 telephone number.

11)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

AIDS Healthcare Foundation
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Medical Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
City Council and City of Compton
Consumers Union
County of San Joaquin
Health Access California
Lieutenant Governor Cruz Bustamante
NAMI California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Opposition

BIOCOM
California Chamber of Commerce
California Health Institute
Pharmaceutical Research and Manufacturers of America

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

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AMENDED IN ASSEMBLY APRIL 6, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 74

Introduced by Assembly Members Gordon and Frommer
(Coauthors: Assembly Members Chavez, Koretz, Laird, Matthews, Pavley, Ridley-Thomas, and Ruskin)

January 3, 2005

An act to add Article 5 (commencing with Section 110243) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 74, as amended, Gordon. California ~~Rx~~ *Rx* Prescription Drug Hotline.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

This bill would require the department to establish the California ~~Rx~~ *Rx* Prescription Drug Hotline, on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) Increased spending on prescription drugs is a significant driver of increases in overall health care costs.

(c) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as federal government statistics show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(d) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that period.

(e) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy.

(f) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Article 5 (commencing with Section 110243) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Precription Drug Hotline

110243. (a) The State Department of Health Services shall establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

(b) The department shall establish a low-cost 1-900 telephone number on or before July 1, 2006. Callers shall be provided *with* information about options for obtaining prescription drugs at affordable prices. The cost per call to the hotline shall not exceed

50 cents ($0.50) and the hotline shall, at a minimum, provide information about all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Federal programs that provide drugs at discounted prices for United States residents.

(4) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(5) Other informational resources as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including, but not limited to, both of the following:

(A) Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

(B) Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.

(6) Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by all of the following:

(A) Licensed pharmacies in the state.

(B) Licensed pharmacies in other states.

(C) Pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

(c) The department shall ensure that the hotline established pursuant to this section is coordinated with and does not duplicate other state-funded programs and services that provide information about prescription drug options and costs.

(d) Any information provided via the hotline shall first be approved by professional staff of the department.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 74 **VERSION: AMENDED APRIL 6, 2005**

AUTHOR: GORDON **SPONSOR: GORDON**

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: CALIFORNIA RX PRESCRIPTION DRUG HOTLINE

Existing Law:

The Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the California Department of Health Services (DHS). (H&S 109875)

This Bill:

1) Requires the DHS to establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the following information:

a. Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

b. State programs that provide drugs at discounted prices for California residents.

c. Federal programs that provide drugs at discounted prices for United States residents.

d. Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

e. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

f. Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.

g. Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by 1) licensed pharmacies in the state, 2) licensed pharmacies in other states, and 3) pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

(H&S 1010243 Added)

Comment:

1) Author's Intent. The author's intent is to provide a one-stop-shop for information on how to obtain low priced prescription drugs. While much of this information is available on the Internet, the author is concerned that it's not getting to senior citizens, many of which who have never used a computer, let alone Internet.

As introduced, the measure would require DHS to establish a 1-900 telephone number for the program. The author is considering amending the bill to link the new program to an existing program and established 1-800 number. One option would be to link the program to the Health Insurance Counseling and Advocacy Program (HICAP), within California Department of Aging. HICAP assists individuals and families with Medicare problems and provides information on Medicare, Medicare supplement insurance, managed care, long-term care planning and health insurance.

2) Oversight. One of the many roles a pharmacist fills is acting as a second check for prescribers to insure that the medication a patient has been prescribed is the right medication for the patient's health condition, and that multiple medications will not adversely interact with each other to negatively effect a patient's health. As patients see specialist doctors for multiple health problems, the pharmacist's oversight role become increasingly more important, as any one doctor may not be aware of all the prescription drugs a patient is taking. Additionally, as patients seek lower cost drugs from more than one source (mail order, Internet, or local pharmacy), they will loose the benefit of one pharmacy or pharmacist knowing all the medications a patient is taking and ensuring that the medications will not result in harm to the patient. AB 74 and other bills that direct patients to multiple sources to obtain low cost drugs, may have the unintended result of putting peoples health at risk.

3) Drug Pricing. This bill requires DHS to provide price comparisons of commonly prescribed brand name prescription drugs, including typical prices charged by instate pharmacies, pharmacies in other states, and pharmacies in Canada. The problem with this requirement is it is impossible to come up with a "typical price charged" for a given drug. The true cost of a drug is influenced by factors including, but not limited to: discounts, rebates, and reimbursement formulas available to a particular purchaser, the number of manufacturers producing a given drug, and the supply and demand for a given drug in a given geographical area. In an effort to establish a benchmark for prescription drugs, standardized terms have been developed, however each term is limited in its ability to accurately establish the true price of prescription drugs. These terms include: average manufacturer price, average sales price, average wholesale price, federal supply schedule, and wholesale acquisition cost.

4) Proposed Amendments.

a. Require people staffing the Hotline to refer callers to legal sources for obtaining prescription drugs and specify that it is illegal to import drugs from outside the United States.

b. Require people staffing the Hotline to discuss the importance of one pharmacist reviewing all the medications a patient is taking, and if a person obtains their medications from multiple sources the person should seek out a pharmacist that can review all their medications.

c. Specify that the price comparison of 50 commonly prescribed drugs be based on both the Medi-Cal price and cash price paid for prescription drugs.

5) History.

2005

Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 10. Noes 4.) (April 12).
Apr. 7	Re-referred to Com. on HEALTH.
Apr. 6	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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BILL ANALYSIS
AB 74

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 74 (Gordon) - As Amended: April 6, 2005

SUBJECT : California Rx Prescription Drug Hotline.

SUMMARY : Establishes the California Rx Prescription Drug Hotline to provide information about affordable prescription drug prices. Specifically, this bill :

1)Requires the Department of Health Services (DHS) to establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2)Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006. Requires the cost per call to be 50 cents or less.

3)Requires the hotline to provide at a minimum information about all of the following:

a) Prescription drug benefits available to Medicare beneficiaries;

b) State programs that provide drugs at discounted prices for California residents;

c) Federal programs that provide drugs at discounted prices for United States residents;

d) Pharmaceutical manufacturer patient assistance programs;

e) Other informational resources deemed appropriate by DHS, including, but not limited to, both of the following:

i) Information regarding the availability of prescription drugs from Canada that meet standards and regulations prescribed by the state or federal government; and,

ii) Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies; and,

f) Price comparisons of at least 50 commonly prescribed

brand name prescription drugs, including typical prices charged by all of the following:

i) Licensed pharmacies in the state;

ii) licensed pharmacies in other states; and,

iii) Pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

4)Requires DHS to ensure that the hotline established pursuant to this bill is coordinated with and does not duplicate other state funded programs and services that provide information about prescription drug options and costs.

5)Requires any information provided via the hotline to first be approved by DHS professional staff.

EXISTING LAW provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of DHS.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill is needed to provide Californians, especially seniors, with a non-web based alternative for finding affordable prescription drugs. With the average price of a prescription about $54.00 and with many people needing multiple prescriptions on a chronic basis, seniors especially face tough choices. The author notes there are a multitude of programs offered by a variety of sources to provide relief from high drug prices, but most seniors are unaware of these programs or put off by complex enrollment processes. Because studies show that only 40% of seniors have ever used a computer and even fewer have ever gone online to access information, the author believes it is critical to offer telephone access to information about affordable prescription drugs.

2)BACKGROUND . Spending on prescription drugs grew at a real (inflation-adjusted) average annual rate of 14.5 percent from 1997 to 2002. That rapid growth raised prescription drug spending's share of total health expenditures to 11% in 2003, compared with 5.8% a decade earlier. In 2003, American consumers paid $53.2 billion in out-of-pocket costs for prescription drugs, an increase of 26% over 2001.

Californians without drug coverage have been especially hard

hit. Some must choose between food, rent, and needed medications. A 2003 Kaiser Family Foundation survey found that 37% of the uninsured, when they finally did see a doctor, did not fill a needed prescription because of cost. Even those with drug coverage, especially through Medicare HMOs and Medicare Supplement policies, find the cost of prescription drugs often far exceeds their coverage limits. Other insured Californians are hit with 3-tiered drug benefits, increased cost-sharing and decreased access to needed drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20% and experienced higher rates of emergency room visits and hospital stays. The Medicare Prescription Drug and Modernization Act of 2003 (MMA) will provide some relief to seniors when it takes effect on January 1, 2006. Even then many seniors will be responsible for significant out-of-pocket expenses. For instance, a senior with $5100 in drug spending will be responsible for $3600 of that amount in addition to an annual premium of at least $420.

3)SUPPORT . Supporters argue that this bill will assist consumers, especially those without internet access, to find affordable prescription drugs and that this bill is an essential complement to web-based legislation.

4)PREVIOUS LEGISLATION . AB 1957 (Frommer) of 2004 would have required DHS to establish a Web site to facilitate purchasing prescription drugs at reduced prices and would also have included links to Canadian pharmacies. SB 1149 (Ortiz) of 2004 would have required the Board of Pharmacy to establish a Web site to facilitate purchasing prescription drugs at reduced prices and would also have included links to Canadian pharmacies. AB 1957 and SB 1149 were vetoed by the Governor.

5)RELATED LEGISLATION . AB 73 (Frommer) requires DHS to establish a Web site to facilitate purchasing prescription drugs at reduced prices and requires the Web site to include price comparisons, including prices of, and links to, international pharmacies that meet specified requirements.

6)COMMENT . It is unclear how this hotline will work operationally. The author may wish a more detailed explanation in the bill.

7)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

AIDS Healthcare Foundation
American Fed. of State, Co., and Municipal Employees
California Federation of Teachers
California Medical Association
California Primary Care Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
County of San Joaquin
Health Access California
OURx Bill of Rights Coalition
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Opposition

None on file.

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

AMENDED IN SENATE JANUARY 6, 2005

SENATE BILL No. 19

Introduced by Senator Ortiz
(Principal coauthor: Senator Poochigian)

December 6, 2004

An act to add Division ~~113~~ *112* (commencing with Section 130600) to the Health and Safety Code, relating to ~~prescription drugs~~ *pharmacy assistance* , and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi–Cal program, and is authorized, among other things, to enter ~~in to~~ *into* contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufactures are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California ~~Rx Program, to be administered by~~ *Pharmacy Assistance Program (Cal Rx) under the oversight of* the department. The bill would authorize the department to *implement and administer Cal Rx through a contract with a 3rd–party vendor or utilizing existing health care service provider enrollment and payment mechanisms. The bill would require the department or 3rd–party vendor to attempt to* negotiate drug rebate agreements *for Cal Rx* with drug manufacturers ~~to provide for program drug discounts~~. The bill would authorize any licensed pharmacy ~~or~~ *and any* drug manufacturer , *as defined,* to provide services under ~~the program~~ *Cal Rx* . The bill would establish eligibility criteria and application procedures for California residents to participate in ~~the program~~ *Cal Rx. The application process would*

require an applicant to attest to information provided under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. The bill would authorize the department to terminate the program if any one of 3 determinations are made .

The bill would establish the California ~~Rx~~ *State Pharmacy Assistance* Program Fund ~~, as a continuously appropriated fund,~~ into which all payments ~~directly~~ received under ~~the program~~ *Cal Rx* would be deposited. *The bill would continuously appropriate the fund to the department for purposes of Cal Rx.*

~~The bill would appropriate $3,000,000 from the State Treasury to the department to fund staff and contract costs for the program.~~

~~The Pharmacy Law is administered by the California State Board of Pharmacy in the Department of Consumer Affairs.~~

~~This bill would require the Department of Consumer Affairs to implement, as a part of the California Rx Program that would be established under the bill, a Prescription Drug Resource Center Web site to educate California consumers about options for lowering prescription drug costs.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: ~~no~~.

The people of the State of California do enact as follows:

~~SECTION 1. Division 113 (commencing with Section 130600) is added to the Health and Safety Code, to read:~~

SECTION 1. Division 112 (commencing with Section 130600) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

CHAPTER 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.

(b) "Cal Rx" means the California State Pharmacy Assistance Program.

(c) "Department" means the State Department of Health Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(h) "Manufacturers rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(i) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(j) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third–party payer program.

(k) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.

(l) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

(m) "Third–party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third–party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi–Cal program's fiscal intermediary.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty

guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third–party payer.

(B) The Medi–Cal program.

(C) The children's health insurance program.

(D) The disability medical assistance program.

(E) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare.

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third–party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi–Cal program, children's health insurance program, or disability medical assistance program.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

130606. (a) The department or third–party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the applicable form is fifteen dollars ($15).

(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx, through a Web site or call center staffed by trained operators approved by the department, or through the third–party vendor. A pharmacy, physician office, clinic, or third–party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

(e) The department or third–party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third–party vendor to enroll applicants in Cal Rx.

(f) During normal hours, the department or third–party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third–party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department or third–party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

130607. (a) The department or third–party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

(b) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.

(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

(c) For those drugs available pursuant to subdivision (a), the department or third–party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

(d) The recipient identification card issued pursuant to subdivision (g) of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions (a) and (d) of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b) may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform

residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable manufacturers rebate.

(c) The department or third–party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third–party vendor.

(d) The department or third–party vendor shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in

Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).

(e) The department or third–party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third–party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third–party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, the department or third–party vendor shall attempt to negotiate drug rebate agreements for Cal Rx with drug manufacturers.

(b) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

(8) Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

(e) The department or third–party vendor may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

(f) Drug rebate contracts negotiated by the third–party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.

(g) The third–party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third–party vendor.

130619. (a) The department or third–party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130620. (a) The department or third–party vendor shall deposit all payments received pursuant to Section 130618 into the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund

is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.

(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

(b) Change orders entered into pursuant to this division shall not require a contract amendment.

130624. The department may terminate Cal Rx if the department makes any one of the following determinations:

(a) That there are insufficient discounts to participants to make Cal Rx viable.

(b) That there are an insufficient number of applicants for Cal Rx.

(c) That the department is unable to find a responsible third–party vendor to administer Cal Rx.

130625. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes

the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

All matter omitted in this version of the bill appears in the bill as introduced in Senate, December 6, 2004 (JR11)

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 19 **VERSION: AMENDED JAN 6, 2005**

AUTHOR: ORTIZ **SPONSOR: GOVERNOR**

RECOMMENDED POSITION:

SUBJECT: California Rx Program

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California State Pharmacy Assistance Program (Cal Rx, program) within the Department of Health Services (DHS). (H&S 130600 Added)

2. Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130602 Added)

3. Defines the terms: benchmark price, Cal Rx, fund, inpatient, lowest commercial price, manufacturer, manufacturers rebate, prescription drug, private discount drug program, recipient, resident, and third-party vendor. (H&S 130600 Added)

4. Establishes eligibility criteria for the program as:

   a. A resident of California who has a family income does not exceed 300 percent of the federal poverty guidelines. (2005 - $28,710 for an individual and $58,050 for a family of four)

   b. A family that does not have outpatient prescription drug coverage.

   (H&S 130605Added)

5. Set a yearly fee of $15 for application or reapplication for the program. (H&S 130606 Added)

6. Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within four hours of receipt of a completed application. (H&S 130606 Added)

7. Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program, if funds are available. (H&S 130615 Added)

8. Requires DHS or third party vendor to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. (H&S 130618 Added)

9. Sets the amount a recipient pays for a drug within program as equal to the pharmacy contract rate, plus a dispensing fee that shall be negotiated by DGS, less the applicable manufacturers rebate. (H&S 130616 Added)

10. Permits DHS to terminate Cal Rx if the department makes any one of the following determinations:

a. That there are insufficient discounts to participants to make Cal Rx viable.

b. That there are an insufficient number of applicants for Cal Rx.

c. DGS is unable to find a responsible third-party vendor to administer Cal Rx. (H&S 130624 Added)

Comment:

1) Author's Intent. This bill is sponsored by the Governor and is in response to last year's veto of SB 1149 (Ortiz 2004). In his veto message the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($28,710 for an individual and $58,050 for a family of four) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx."

A fact sheet issued by the author's office states "In addition to the discounted drugs available to Cal Rx participants, Governor Schwarzenegger has secured a commitment from the Pharmaceutical Researchers and Manufacturers Association (PhRMA) to provide $10 million over the next two fiscal years to fund a clearinghouse to publicize and help Californians enroll in manufacturers' free and discount programs. The clearinghouse will provide Internet access and a toll-free multi-lingual call center to help thousands of Californians receive prescription drugs absolutely free, thereby saving them hundreds of millions of dollars per year. This element of the program does not require legislation and will begin operating in Spring 2005."

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation. AB 74 (Gordon) California Rx Prescription Drug Hotline. This measure would require DHS to establish a drug hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

AB 73 (Frommer) Safe and Affordable Drug Importation from International Pharmacies, would require DHS to set up a web site that would provide information on importing drugs from international pharmacies.

AB 75 (Frommer) Pharmaceutical Assistance Program, establishes the California Rx Plus State Pharmacy Assistance Program within DHS. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure stablishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines.

AB 76 (Frommer) Office of Pharmaceutical Purchasing. This measure would instead establish within the California Health and Human Services Agency, the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies. The bill would authorize the office to conduct specified activates in order to negotiate the lowest prices possible for prescription drugs.

5) Support / Opposition.

Support: AARP
California Medical Association
California Pharmacists Association
AIDS Healthcare Foundation
Parkinson's Action Network
American Academy of Pediatrics
California Chamber of Commerce
Northeastern California Chapter, California Arthritis Foundation Council
California Academy of Family Physicians
California Council of the Alzheimer's Association
California Psychiatric Association
Mental Health Association in California
California Hepatitis C Task Force
Epilepsy Foundation of Nor. California

Hemophilia Foundation of No. California
American College of Obstetricians and Gynecologists

Opposition: California Labor Federation
California Alliance for Retired Americans

5) History.

2005	
Apr. 14	Set for hearing April 20.
Apr. 13	Testimony taken. Hearing postponed by committee.
Mar. 17	Set for hearing April 13.
Jan. 27	To Com. on HEALTH.
Jan. 6	To Com. on RLS. From committee with author's amendments. Read second time. Amended. Re-referred to committee.
2004	
Dec. 7	From print. May be acted upon on or after January 6.
Dec. 6	Introduced. Read first time. To Com. on RLS. for assignment. To print.

BILL ANALYSIS
SB 19

SENATE HEALTH
COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

AUTHOR: Ortiz

AMENDED: January 6, 2005
and as proposed to be amended

HEARING DATE: April 13, 2005

FISCAL: Appropriations

CONSULTANT:
Bohannon / ak

SUBJECT

California Rx Program

SUMMARY

This bill would establish the California State Pharmacy Assistance Program (Cal Rx), a state pharmacy assistance program under the authority of the Department of Health Services (DHS), to provide prescription drug discounts for California residents with income up to 300% of the federal poverty level (FPL).

ABSTRACT

Existing federal law:
1.Requires, for the purposes of the federal Medicaid program, drug manufacturers to enter into rebate agreements with the United States Secretary of Health and Human Services (the Secretary) for states to receive federal funding for outpatient prescription drugs dispensed to Medicaid enrollees.

2.Defines Medicaid "best price" as the lowest price paid to a manufacturer for a brand name drug, taking into account rebates, chargebacks, discounts or other pricing adjustments, excluding nominal prices.

3.Requires manufacturers under agreement with the Secretary to provide rebates to state Medicaid agencies for outpatient prescription drugs provided to Medicaid beneficiaries. For brand name drugs, requires the amount of the rebate owed to be the greater of 15.1% of the

average manufacturers price (AMP) or the difference between AMP and the best price. Requires rebates for generic drugs to be 11% of AMP.

4. Excludes the prices charged to certain governmental purchasers from best price provisions including prices charged to the Veterans Administration, Department of Defense, Indian tribes, Federal Supply Schedule, state pharmaceutical assistance programs (SPAPs), Medicaid, and 340B covered entities.
5. Permits a state, upon authorization from the Secretary, to enter directly into agreements with drug manufacturers to negotiate deeper (supplemental) discounts for state Medicaid programs.

6. Specifies that a state may require, as a condition of coverage or payment for a covered outpatient drug, the approval of the drug before its dispensing if the system of providing for such approval meets specified criteria.

Existing federal guidance:
1. Authorizes states to establish SPAPs for the purposes of providing pharmaceutical benefits for low-income non-Medicaid eligible residents.

2. Establishes the following criteria for federal SPAP designation:

The program is a state developed program specifically for disabled, indigent, low-income elderly or other financially vulnerable persons;

The program is funded by the state; that is, no federal dollars are involved;

The program is set up so that payment is provided directly to the providers;

The program provides either a pharmaceutical benefit only or a pharmaceutical benefit in conjunction with other medical benefit or services; and,

The program does not allow for the diversion, resale or transfer of benefits reimbursed under the SPAP to individuals who are not beneficiaries of the STAP.

Existing state law:
1. Establishes the Medi-Cal program, California's Medicaid program, which provides health insurance coverage and prescription drug benefits for low-income families,

children, and aged, blind, and disabled individuals.

2.Authorizes DHS to be the purchaser of prescribed drugs under the Medi-Cal program in order to obtain the most favorable prices from drug manufacturers. Authorizes DHS to obtain discounts, rebates, or refunds based on the quantities purchased by the program, as permissible by federal law.

3.Defines "state rebate" as any negotiated rebate under the Drug Discount Program (Medi-Cal) in addition to the Medicaid rebate.

4.Authorizes DHS to enter into contracts with drug manufacturers, on a bid or nonbid basis, for drugs from each therapeutic category and requires DHS to maintain a list of those drugs for which contracts have been executed.

5.Authorizes DHS or the state's fiscal intermediary to impose prior authorization requirements on the drug products of manufacturers for which DHS has not received rebate or interest payments as specified.

6.Exempts specified drugs from prior authorization requirements and authorizes the director of DHS to exempt any drug from prior authorization if it is determined that an essential need exists for that drug and there are no other drugs available without prior authorization that meet that need.

7.Requires all manufacturers to provide DHS with a state rebate, in addition to rebates pursuant to other provisions of state or federal law, for any drug products added to the Medi-Cal list of contract drugs and those reimbursed through the Medi-Cal outpatient fee-for-service drug program. Renders this provision inoperative on July 1, 2005 and repealed January 1, 2006, unless otherwise extended or repealed.

8.Authorizes DHS to use existing administrative mechanisms for any drug for which DHS does not obtain a rebate.

9.Provides that no beneficiary be denied continued use of a drug that is part of a prescribed therapy that is the subject of an administrative mechanism until the prescribed therapy is no longer prescribed.

This bill:
1.Establishes Cal Rx, a SPAP, under the authority of DHS.

2.Provides that to be eligible for Cal Rx, individuals must meet all of the following requirements:

Be a resident;

Have family income that does not exceed 300% of FPL;

Not have outpatient prescription drug coverage paid for in part or in whole by a third-party payer (exempts individuals who have reached the annual cap on their prescription drug coverage), the Medi-Cal program, the children's health insurance program, another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of an individual's outpatient prescription drug costs.

Medicare beneficiaries may participate to the extent allowed by federal law and SPAP standards for prescription drugs not covered by Medicare prescription drug coverage or those currently responsible for paying 100% of the cost of a prescription drug under the coverage gap provisions of the Medicare prescription drug benefit.

Not have had outpatient prescription drug coverage during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, with certain exceptions.

1.Requires application and annual reapplication and establishes program application criteria and procedures. Specifies that the application and annual reapplication fee due upon submission through a pharmacy, physician office, or clinic is $15.

2.Requires DHS to use the income information reported on the application and not require additional documentation.

3.Authorizes a pharmacy, physician office, or clinic to keep the fee as reimbursement for its processing costs. The fee shall be returned to the applicant if the applicant is already enrolled in Cal Rx.

4.Specifies that application and annual reapplication may also be made through a Web Site or call center staffed by trained operators approved by DHS.

5.Requires DHS or a third party vendor to utilize a secure electronic application process that can be utilized to enroll applicants in Cal Rx.

6.Requires DHS or a third party vendor, during regular business hours, to make an eligibility determination within 4 hours of receipt of a Cal Rx completed application.

7. Requires applicants to certify under penalty of perjury that the information in the application is true.

8. Requires DHS to encourage participating manufacturers to maintain their private discount drug programs at a level comparable to which they were offered prior to the enactment of Cal Rx and, to the extent possible, simplify the application and eligibility processes for those programs.

9. Requires DHS or a third party vendor to attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those programs.

10. Prohibits an applicant from having to disclose information that would determine eligibility for a private drug discount program in order to participate in Cal Rx.

11. Requires DHS or a third party vendor to develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private drug discount programs.

12. Requires the recipient to be issued an identification card, which shall meet the legal requirements for a uniform prescription drug card.

13. Requires DHS to conduct outreach programs to the extent that funds are available. Prohibits the outreach material from containing the name or likeness of a drug. Specifies that the name of the organization sponsoring the material may appear on the material once and in a font no larger than 10 point.

14. Allows DHS to accept, on behalf of the state, any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Exempts these gifts and advertisements provided as gifts as specified.

15. Authorizes DHS to negotiate a contract with any manufacturer to provide funds as grants to nonprofit programs for the purpose of conducting outreach for Cal Rx.

16. Authorizes any licensed pharmacy and manufacturer, as defined, to participate in Cal Rx.

17. Specifies that the amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate, as defined, plus a dispensing fee, less the applicable manufacturers rebate.

18. Requires DHS or a third party vendor to provide a claims processing system as specified.

19. Requires DHS to attempt to negotiate manufacturer rebate agreements for Cal Rx with drug manufacturers. Requires DHS to pursue manufacturer rebate agreements for all drugs in each therapeutic category.

20. Requires each participating manufacturer rebate agreement to:

Specify which drugs are included in the agreement.

Permit DHS to remove a drug from the agreement in a dispute over the drug's utilization.

Require the manufacturer to make a rebate payment for each drug specified.

Require the rebate payment for a drug be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

Define a unit, for the purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

Require the manufacturer to make the rebate payments to DHS on at least a quarterly basis.

Require the manufacturer to provide documentation to validate the per unit rebate.

Require the manufacturer to report to DHS the lowest commercial price, as specified, for each drug available through Cal Rx.

Require the manufacturer to pay interest on late or unpaid rebates.

Permit a manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx.

Contain provisions for the timely reconciliation of payment of rebates and interest penalties on disputed units.

Permit DHS to audit or review manufacturer records and contracts as necessary.

1.Authorizes DHS to limit the number of drugs available within Cal Rx to obtain the most favorable discounts.

2.Authorizes DHS to contract with private or public purchasing groups to obtain the most favorable discounts on multiple-source drugs.

3.Requires the entire amount of the negotiated drug rebates

to go towards reducing the cost to Cal Rx recipients of

4. Authorizes DHS or a third party vendor to collect prospective rebates from manufacturers for payment to pharmacies. Authorizes a third party vendor to directly collect rebates from manufacturers in order to facilitate the payment to pharmacies. Requires DHS to develop a system to prevent the diversion of funds.

5. Requires participating manufacturers to calculate and pay interest on late or unpaid rebates, which shall begin accruing 38 calendar days from the date of mailing the quarterly invoice.

6. Specifies that interest rates and calculations shall be "X" percent.

7. Requires participating manufacturers to clearly identify all rebates, interest, and other payments for Cal Rx in a manner designated by DHS.

8. Requires DHS or a third party vendor to generate a monthly report as specified.

9. Establishes the California State Pharmacy Assistance Program Fund in the State Treasury and requires DHS or a third party vendor to deposit all payments received as specified.

10. Specifies that moneys in the fund are appropriated to DHS without regard to fiscal years for the purpose of providing payment to participating pharmacies and for defraying the costs of administrating Cal Rx. Specifies that no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

11. Requires that interest earned on rebates collected from participating manufacturers also be deposited in the fund exclusively to cover costs related to the purchase of drugs through Cal Rx.

12. Authorizes DHS to hire any staff needed for the implementation and oversight of Cal Rx.

13. Requires DHS to seek and obtain confirmation from the Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a SPAP.

14. Exempts contracts and change orders entered into from competitive bidding requirements and specified provisions

of the Public Contract and Government Codes.

15. Specifies that change orders entered into shall not require contract amendment.

16. Exempts drug rebate contracts entered into from disclosure under the Public Records Act.

17. Permits the director to implement this division in whole or in part by means of provider bulletin or other similar instructions, without taking regulatory action.

18. Requires that no reimbursement be required pursuant to Section 6 of Article XIII B of the California Constitution.

FISCAL IMPACT

The Governor's FY 05-06 budget plan for DHS appropriates $3.9 million dollars from the General Fund for program staff and administrative costs. Unknown one-time costs associated with the timing of rebates and initial payments to pharmacies.

BACKGROUND AND DISCUSSION

Rising prescription drug costs
As a number of studies document, access to affordable prescription drugs is a growing problem in California and in the US. According to the Kaiser Family Foundation (KFF), almost a quarter of Americans under age 65 have no prescription drug coverage. In California, according to the UCLA Center for Health Policy Research, nearly one in five Californians under age 65 lacked health coverage altogether in 2001, a substantial percentage of whom are not eligible for most public assistance or drug assistance programs due to excess income or assets. Of those who do have health coverage, over 2 million report that they do not have coverage for prescription drugs.

Further, prescription drugs represent one of the fastest growing health care expenditures as drug prices continue to grow at roughly twice the rate of inflation in California and the rest of the U.S. Of the 50 drugs used most frequently by seniors, the average annual cost as of January 2003 was $1,439. The five most frequently prescribed medications for the elderly all had annual costs of between $500 and $1,500 per year. According to surveys, substantial percentages of seniors forego taking their medications due to the high cost.

Canadian importation

In an effort to facilitate immediate access to affordable prescription drugs for seniors and people with disabilities, several members of the legislature introduced bills that would have allowed the importation of prescription drugs from Canada in some capacity. Although it is currently illegal, an estimated 1 million Americans buy drugs from Canada, accounting for at least $1 billion in annual sales. According to various sources, comparable drugs in Canada sell for 40 percent less than in the U.S. on average, and can sometimes sell for 50 - 70 percent less, because the Canadian government limits what drug companies can charge for prescription drugs. In addition, exchange rates can contribute to lower costs of Canadian drugs.

The Food and Drug Administration's (FDA) consistent policy has been that foreign medicines are unsafe because they cannot assure that they are not counterfeit, mislabeled, expired, or contaminated. Although it cannot point to cases in which US residents have been harmed by drugs purchased from foreign pharmacies, the FDA cites evidence from several border checks of drugs bound for consumers in the US that have found large percentages of unidentified drugs, counterfeit drugs, mislabeled drugs, and drugs not approved for use in the U.S.

The FDA has adopted a personal importation policy which permits individuals and physicians to import up to a three-month supply of drugs for treatment of a patient's condition for which effective treatment may not be available domestically, which do not present an unreasonable risk, and for which there is no intent to market to U.S. residents. In practice, the FDA generally has not prosecuted individuals who are importing drugs for their own use.

In a letter dated August 19, 2004, the Secretary of the Health and Human Services Agency expressed concern that the importation measures were contrary to federal law and would expose the state to potential tort liability. As an alternative approach, the Secretary proposed amending the bills to establish a SPAP to harness the purchasing power of low-income seniors and uninsured Californians to secure prescription drug discounts from pharmaceutical manufacturers.

Governor Arnold Schwarzenegger, subsequently, sent a letter to Tommy Thompson, Secretary of the U.S. Department of Health and Human Services, detailing his concern with the Canadian drug importation legislation and expressing his

desire to reduce the costs of prescription drugs by establishing a drug discount program or by extending Medi-Cal prescription drug prices to targeted low-income uninsured residents.

On September 21, 2004, the Senate Health and Human Services Committee held an informational hearing on the Administration's pharmacy assistance proposal where representatives from DHS provided a detailed overview of the proposal including the estimated discounts, number of enrollees, and timeline for implementation. The committee also heard extensive testimony from representatives from senior and consumer advocacy organizations who believed the administration's proposal needed considerably more work before it could provide the band of discounts available under a Canadian importation model.

State Pharmaceutical Assistance Programs (SPAPs)
SPAPs refer to a broad category of state policies designed to help residents pay for prescription drugs. States submit program proposals meeting specified criteria to the federal government in order to receive a SPAP designation. This designation incentivizes manufacturer participation by exempting the prices the state negotiates for program beneficiaries from Medicaid "best price" laws, thereby allowing the state to negotiate deeper drug discounts. As of August 2004, at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number use discounts or bulk purchasing approaches. Many of these programs were established prior to the enactment of the Medicare prescription drug benefit and provide an opportunity for states to provide "wrap around" coverage to Medicare beneficiaries who will be receiving prescription drug benefits under Medicare. SPAPs usually provide discounts using the following mechanisms:

Medicaid Rate. Enrollees will pay no more than the state's Medicaid price. An additional pharmacy dispensing fee may be added to the drug price, but that is generally set by the program and, therefore, the same across all pharmacies. Enrollees will pay the same amount for a particular manufacturer's drug at all pharmacies that participate in the program.

Manufacturer Rebates. Some states will negotiate directly with manufacturers for lower drug prices. These

states then set a drug price for program enrollees that are based on the state-negotiated price.

Medicaid Rebate. The drug discount is based on the manufacturers' rebates through the state's Medicaid programs.

Pharmacy Benefits Manager (PBM)-Negotiated Rate. The PBMs negotiate discounts with manufacturers and pharmacists. If the state uses multiple PBMs, the discounted price will vary.

Maine and the Medicaid "Hammer"
Maine's Act to Establish Fairer Prices for Prescription Drugs was enacted in 2000, and established the MaineRx program, which was open to all residents who did not have prescription drug coverage. Under MaineRx, the state was to serve as a PBM by negotiating rebates and discounts, with the discount offered by pharmacies being reimbursed by the state out of funds raised from participating manufacturer rebates.

Pharmacy participation was voluntary, but compulsory for manufacturers with Medicaid contracts in the state. MaineRx provided disincentives for nonparticipating manufacturers, such as subjecting their drugs to prior authorization requirements in the state Medicaid program (the "hammer") and advertising their refusal to participate to health care providers and the public.

MaineRx was immediately challenged by the pharmaceutical industry. PhRMA sued the state, won a preliminary injunction from the federal district court, and then lost a subsequent appeal by the state before a federal court of appeals panel. In particular, the appellate court rejected PhRMA's argument that MaineRx's prior authorization requirement was inconsistent with federal Medicaid law. The appellate court further found that the local benefits of the program outweighed any incidental burdens on interstate commerce. In July 2001, PhRMA asked the U.S. Supreme Court to review the decision.

On May 19, 2003, the U.S. Supreme Court ruled 6 to3 that the MaineRx Program was not preempted because the Medicaid Act "gives the States substantial discretion to choose the proper mix of amount, scope and duration limitations on coverage, as long as care and services are provided in the best interest of the recipients." The Court also ruled that the MaineRx statute on its face did not violate the Interstate Commerce Clause.

The legislature revised MaineRx soon after the Supreme Court acted by creating the MaineRx Plus program. The new program requires participating pharmacies to provide drugs that are on Maine's Medicaid preferred drug list to state residents whose family income is 350% or less of the FPL or whose family incurs unreimbursed prescription drug expenses equal to 5% or more of family income or unreimbursed medical expenses of 15% or more of family income.

As of January 2004, pharmacies began providing drugs to MaineRx Plus participants at the same cost as Medicaid participants pay. If the state is able to negotiate further discounts, pharmacies must offer the drugs at this lower price, and the state must reimburse them for the price difference. The new program does not include the $3 dispensing fee that pharmacies were to receive under MaineRx.

The MaineRx law required the state to impose prior authorization requirements in its Medicaid program on drug manufacturers and drug labelers that did not participate in the program. MaineRx Plus softens this somewhat, by removing the mandatory requirement and instead granting the state the authority to impose prior authorization if DHS determines that doing so is an appropriate way to encourage manufacturer participation and is consistent with the state Medicaid plan and federal law. It makes the names of manufacturers and labelers who do not provide rebates public information and requires DHS to release them to the public and health care providers. The names of manufacturers and labelers who provide rebates also become public, and DHS is supposed to publicize their participation. As with MaineRx, the manufacturers' rebates are to be paid into a dedicated fund that is used to reimburse pharmacies for the drug discounts and DHS for contracted services related to the program, including pharmacy claims processing fees.

In January 2005, the Federal District Court in Maine ruled that under the legal doctrine of "ripeness," it would be premature to conclude that the permissive prior authorization scheme in MaineRx Plus in any way violates federal Medicaid law; that we cannot know this unless and until it is actually applied and we can factually determine whether any Medicaid beneficiaries were hurt by its use. The court stated that since the Maine statute explicitly requires prior authorization be implemented only "as permitted by law" and "in a manner consistent with the goals of the MaineCare program and the requirements of the

Social Security Act," it is possible for Maine to implement its prior authorization without violating the law. The court concluded that while the Maine program was not reviewable at this time, due to lack of ripeness, it remains subject to review by the Secretary of Health and Human Services at the appropriate time.

Arguments in support
Supporters of the bill, including AARP, the California Medical Association, and several disease management groups across the state insist that SB 19 is an important first step in providing significant and immediate relief to those who are paying the highest costs for their prescription drugs. They insist that the proposal will deliver discounts of 40% to 70% off the retail price of prescription drugs and provide nearly 5 million low-income Californians better access to private drug discount programs which often offer free or deeply discounted prescription drugs.

They believe that Cal Rx is an essential element in the complex care system that will support the needs of seniors and persons with disabilities and chronic conditions who have reduced incomes due to their limited ability to work or in the case of those who are dependant, limited income due to family members who must give their own jobs in order to be caregivers. They insist that the discounts this proposal contemplates should be given the opportunity to materialize before more aggressive measures that could potentially risk the health and well-being of our most vulnerable seniors, children, and persons with disabilities are pursued. They believe that SB 19 is the only legislative proposal that provides the best hope of being implemented quickly and with relatively low risk of litigation.

Arguments in opposition
Opponents of SB 19 raise the following concerns:

1.Lowest commercial price as a benchmark
Opponents believe the lowest commercial price is a fictitious price that is not commonly known and has not been adequately referenced in the bill. They insist that SB 19 should include a more commonly recognized benchmark price such as the Medicaid price for DHS to target in drug company negotiations. They insist that using the Medicaid price would also reduce the administrative overhead required, since the prices of the Medi-Cal program are already known to the state.

2.Income eligibility

Opponents insist that given California's high cost of living, SB 19's income eligibility should be expanded to cover individuals with income up to 400% of the federal poverty level. They insist that many Californians most in need of drug discounts are those who are sick and underinsured. They also believe that individuals who spend significant portions of their incomes on medications also deserve discounted prices.

3.Drug availability
Opponents of the bill argue that SB 19 allows pharmaceutical manufacturers to determine which drugs will be included in the discount program and for what period of time. They believe SB 19 contains no assurance that the drugs that are the highest cost to the uninsured or the most frequently needed by affected populations will be included.

4.Outreach
Opponents of the bill believe that it is problematic to allow DHS to accept branded outreach materials from drug manufacturers for use in a public health program.

5.Lack of Medicaid leverage or "hammer"
Opponents of SB 19 insist that participation by pharmaceutical manufacturers and pharmacists is entirely voluntary leaving the state without a mechanism to punish those who fail to provide drug discounts. They insist that the bill's exclusive reliance on voluntary participation provides little assurance that any drug discounts the state is able to secure will be maintained. They believe that rather than relying on voluntary participation, SB 19 should be amended to allow the state to impose prior authorization requirements in the Medi-Cal program if a drug manufacturer refuses to offer meaningful discounts in Cal Rx.

Prior / relevant legislation

AB 73 (Frommer, 2005) provides information to consumers about international pharmacies that meet state standards for safety and accessibility. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 75 (Frommer, 2005) establishes a state pharmacy assistance program for Californians with income up to 400% of the federal poverty level. Set for hearing in the Assembly Health Committee on April 12, 2005.

AB 76 (Frommer, 2005) consolidates drug purchasing for state programs to negotiate lower drug prices. Set for

hearing in the Assembly Health Committee on April 12, 2005.

AB 77 (Frommer, 2005) creates a pilot program for the California Department of Corrections to purchase prescription drugs at federal discount prices. Set for hearing in the Assembly Health Committee on April 12, 2005.

SB 1333 (Perata, 2004) allowed DHS to reimburse pharmacies for drugs dispensed to Medi-Cal and AIDS Drug Assistance Program beneficiaries that were purchased from a Canadian pharmacy, and established a new reimbursement rate for such drugs. Vetoed by the Governor.

SB 1144 (Burton, 2004) required Canadian sources be included among the companies with which the Department of General Services (DGS) is permitted to contract for prescription drugs, that all contracts include appropriate safeguards, and that DGS seek appropriate federal waivers. Vetoed by the Governor.

SB 1149 (Ortiz, 2004) required the Board of Pharmacy to develop a website that included information on Canadian pharmacies that met recognized standards for safe dispensing of drugs to California residents and information concerning prescription drugs suppliers outside the United States that violated safe dispensing standards. Vetoed by the Governor.

AB 1957 (Frommer, 2004) required DGS to coordinate a review of state agencies to determine potential savings if prescription drugs were purchased from Canada and to establish pilot programs. Required DHS to establish a California Rx Program, including a website to facilitate purchasing prescription drugs at reduced prices. Required the website to include price comparisons, including Canadian prices and links to Canadian pharmacies. Vetoed by the Governor.

QUESTIONS AND COMMENTS

1.The Maine Mystery. The MaineRx Plus program is widely regarded as the vanguard of prescription drug policy at the state level; however the success of MaineRx Plus remains ambiguous. It is currently unclear what level of discounts the program has been able to secure on brand name and generic drugs and to what extent those discounts are derived from manufacturer rebates. Additionally, it is also uncertain whether or not Maine's "hammer", their statutory authority to place the drugs of non-MaineRx

Plus-participating manufacturers on prior authorization in the state Medicaid program, has encouraged or discouraged manufacturer participation.

According to the Legislative Analyst's Office (LAO), Maine's program has secured rebates with 20 drug companies for 200 drugs with prices up to 60% below the retail pharmacy price. However, other sources indicate that the state has only secured discounts of up to 15% for brand name drugs and 60% for generics through voluntary agreements with drug manufacturers, while others maintain that the state has not begun negotiating with drug manufacturers at all.

What is clear, however, is that MaineRx Plus is not an SPAP. Arguably, federal SPAP designation is the "hammer" that incentivizes manufacturer participation and allows states to negotiate deep discounts. If California is able to secure SPAP designation for Cal Rx, the program could negotiate discounts far below what MaineRx Plus is currently able to provide. The LAO recommends a "hybrid hammer" approach whereby, the state would move forward with a voluntary program, but would require the director of DHS to automatically phase out the voluntary model if drug manufacturers fail to participate. In such a circumstance, the eligibility standard for the program would automatically be expanded to 400% of the federal poverty level.

Should this bill be amended to include benchmark and accountability measures to measure manufacturer participation and program discounts over time and to determine whether a more stringent approach is needed?

If such leverage could increase manufacturer participation, secure significantly deeper discounts, and be implemented in such a way that it is consistent with federal law and the goals of the Medicaid program, including preserving prescription drug access for the most vulnerable Medi-Cal beneficiaries, without jeopardizing federal SPAP designation, should it be considered for this proposal?

1. Income Eligibility and Catastrophic Coverage. While 300% of the federal poverty guideline covers more than 75% of California's uninsured, arguably some provision should be made for individuals with higher incomes who, because of chronic conditions, must spend a disproportionate amount of their family income on unreimbursed medical expenses or prescription drug costs. MaineRx Plus extends eligibility to all residents whose family incurs

unreimbursed prescription drug expenses and unreimbursed medical expenses equal to 5% and 15% or more of family income, respectively.

California's AIDS Drug Assistance Program (ADAP), an SPAP for individuals infected with HIV/AIDS, sets program eligibility at 400% of the FPL. ADAP establishes state precedent for moving beyond 300% of the FPL due to exorbitant prescription drug costs and medical necessity.

Federal SPAP designation requires that a program be means tested and specifically designed to serve low-income vulnerable populations. While Maine's generous catastrophic coverage provision would probably not meet federal approval, the author may wish to consider including some form of catastrophic

POSITIONS

Support: State Department of Health Services (sponsor)
AARP
AIDS Healthcare Foundation
Alzheimer's Association
American Russian Medical Association
Asthma & Allergy Foundation of America
BayBio
BIOCOM
California Academy of Family Physicians
California Arthritis Foundation Council
California Black Chamber of Commerce
California Council of Community Mental Health Agencies
California Healthcare Institute
California Hepatitis C Task Force
California Latino Medical Association
California Medical Association
California Pharmacists Association
California Psychiatric Association
California Society of Health-System Pharmacists
Down Syndrome Information Alliance
Epilepsy Foundation
Generic Pharmaceutical Association (if amended)
Gray Panthers California (if amended)
Hemophilia Council of California
Hispanic-American Allergy Asthma and Immunology Association
Lambda Letters Project
Mental Health Association in California
NAMI California
National Multiple Sclerosis Society - California Action Network

Osteopathic Physicians and Surgeons of California
Pharmaceutical Research and Manufacturers of America
TMJ Society of California

Oppose: California Alliance for Retired Americans
Continued---
California Federation of Teachers
California School Employees Association, AFL-CIO

Oppose American Federation of Government Employees, Local 1061 unless American Federation of State, County, & Municipal Employees
Amended: American Federation of Television and Radio Arts
Butchers' Union Local 120
California Conference Board of the Amalgamated Transit Union
California Conference of Machinists
California Labor Federation,
California Nurses Association
California Professional Firefighters
California Public Interest Research Group
California Teamsters Public Affairs Council
Central Labor Council of Butte and Glenn Counties
Central Labor Council of Contra Costa County
Communications Workers of America (CWA), Local 9412
CWA, Local 9415
CWA, Local 9423
CWA, Local 9431
CWA, Local 9503
CWA, Local 9586
Engineers and Scientists of California Local 20, IFPTE
Graphic Communications Union, Local 583
Health Access California
Industrial, Technical and Professional Employees Union, Local 4873
International Alliance of Theatrical Stage Employees, Local 16
International Association of Machinists and Aerospace Workers,
District Lodge 947
International Brotherhood of Electrical Workers (IBEW), Local 6
IBEW, Local 45
IBEW, Local 302
IBEW, Local 441
IBEW, Local 569
International Cinematographers Guild Local 600
Ironworkers Local 433
Ironworkers Local 509

Laborers' International Union of North America
Laborers' International Union of North America, Local 89
National Association of Broadcast Employees and Technicians, Local 53
National Association of Chain Drug Stores
Northern California District Council - ILWU
Office of Professional Employees International Union, AFL-CIO, CLC
Orange County Central Labor Council, AFL-CIO
Plumbers and Pipefitters UA, Local 62
Professional and Technical Engineers, Local 21, IFPTE
Professional Musicians, Local 47
Sailors' Union of the Pacific
San Diego Imperial Counties Labor Council, AFL-CIO
San Francisco Labor Council, AFL-CIO
San Mateo Building and Construction Trades Council
San Mateo County Central Labor Council
Santa Clara & San Benito Counties Building & Construction
Trades Council
Senior Action Network
Service Employees International Union (SEIU), AFL-CIO
SEIU, Local 660
SEIU, Local 1280
SEIU, Local 2028
SEIU of United Healthcare Workers - West
Sheet Metal Workers' International Association Local Union 104
Sheet Metal Workers' International Association Local Union 206
Southern California District Council of Laborers
Strategic Committee of Public Employees, Laborers International Union
Teamsters Local Union 683
Teamsters Local Union 896
Teamsters Local 912
Teamsters Local 853
Teamsters Union Local 572
Teamsters Union Local 601
Tri-Counties Central Labor Council
UFCW Local 1428
UFCW Local 1442
UNITE-HERE! AFL-CIO
UNITE-HERE! Local 19
UNITE-HERE! Local 49

United Professional Firefighters of Contra Costa County,IAFF Local 1230
United Teachers Los Angeles
400 Individuals

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 75

Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members *Baca,* Bass, *Berg, Cohn, Coto, De La Torre,* Evans, *Goldberg,* Gordon, *Hancock, Klehs,* Koretz, *Leno, Levine, Lieber,* Nava, Pavley, *Ridley-Thomas, Ruskin,* ~~and~~ Salinas, *and Torrico*)

January 3, 2005

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 75, as amended, Frommer. Pharmaceutical assistance program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program. *The bill would make it a misdemeanor for a person to intentionally make false declarations as to his or her*

eligibility or eligibility on behalf of any other person seeking eligibility. Because this bill would create a new crime, it would impose a state-mandated local program.

The bill would establish the California Rx Plus Program Fund, as a continuously appropriated fund, into which all payments received under the program would be deposited, with this fund to be used for the purpose of implementing the program.

~~The bill would transfer $5,000,000 from the General Fund to the California Rx Plus Program Fund, thus constituting an appropriation.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

SECTION 1. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA RX PLUS STATE PHARMACY ASSISTANCE PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. (a) This division shall be known, and may be cited, as the California Rx Plus State Pharmacy Assistance Program.

(b) For purposes of this division, the following definitions apply:

(1) "Department" means the State Department of Health Services.

(2) "Fund" means the California Rx Plus Program Fund.

(3) "Manufacturer" means a drug manufacturer, as defined in Section 4033 of the Business and Professions Code.

~~(3)~~

(4) "Program" means the California Rx Plus State Pharmacy Assistance Program.

~~(4)~~

(5) (A) "Qualified resident" means a resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines, as updated periodically in the Federal Register by the United States Department of Health and Human Services under the authority of Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902(2)).

(B) "Qualified resident" also means a resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal 15 percent or more of family income.

(C) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

(6) "Resident" means a resident of California pursuant to Section 17014 of the Revenue and Taxation Code.

130501. There is hereby established in the State Department of Health Services, the California Rx Plus State Pharmacy Assistance Program.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES

130505. (a) To be eligible for the program, ~~an individual~~ *a person* shall be a qualified resident, as defined in paragraph (4) of subdivision (b) of Section 130500 and shall not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program or the Healthy Families Program, *or any other program that uses federal funds to pay part or all of the cost of the person's outpatient prescription drugs.*

(b) ~~An individual~~ *Notwithstanding subdivision (a), a person* enrolled in Medicare may participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare.

130506. (a) The department shall establish application forms and procedures for enrollment in the program. *The application form shall include a requirement that the applicant or the applicant's guardian or custodian attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.*

(b) In assessing the income requirement for program eligibility, the department shall use the income information reported on the application and shall not require additional documentation.

(c) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible shall be guilty of a misdemeanor.

(d) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible may be denied a drug discount card under this program for up to one year from the date of the denial of coverage by the department.

~~(c)~~

(e) Upon determination of eligibility, the department shall mail the qualified resident a California Rx Plus Discount Card.

130507. (a) The department shall execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer patient assistance program.

(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.

(d) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the

department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30–day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(3) The total number of prescriptions or 30-day supplies, and total value, of each of the manufacturer's brand name drugs provided at no or very low cost to California residents during the previous year.

(e) The California Rx Plus Discount Card issued pursuant to subdivision (e) of Section 130506 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130515. *(a)* The department shall conduct an outreach program to inform California residents of their opportunity to participate in the California Rx Plus State Pharmacy Assistance Program. The department shall ~~coordinate outreach activities with~~ *implement an outreach, education, and enrollment program with Health Insurance Counseling and Advocacy Program agencies,* the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program.

(b) The department shall implement a plan to prevent the occurrence of fraud in the program.

130516. (a) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(b) Any drug manufacturer may participate in the program.

130517. (a) The amount a program participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130518. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program.

(b) The department shall seek to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medi-Cal rebate program pursuant to Section 14105.33 of the Welfare and Institutions Code.

~~(b)~~

(c) Upon receipt of a determination from the federal Centers for Medicare and Medicaid Services that the program is a state pharmaceutical assistance program as provided in Section 130522, the department shall seek to contract for drug rebates that result in a net price lower than the Medicaid best price for drugs covered by the program.

~~(c)~~

(d) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

~~(d) No less than 95 percent~~

(e) All of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.

~~130519. (a) To the extent permitted by federal law, and subject to any necessary federal approvals or waivers, the~~

(f) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

(8) Require the manufacturer to calculate and pay interest on late or unpaid rebates. The department may, by regulation, establish the date upon which the interest payments by drug manufacturers shall begin to accrue as well as any other regulations it deems necessary for the implementation of this paragraph.

(g) The department may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in the drug rebate agreements executed pursuant to this section.

130519. (a) The department may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) for any drug of a manufacturer that does not agree to provide rebates to the department for prescription drugs purchased under this division, *to the extent the department determines it is appropriate to do in order to encourage manufacturer participation in the program, and to the extent permitted by federal law, and subject to any necessary federal approvals or waivers.*

(b) The names of manufacturers that do and do not enter into rebate agreements with the department pursuant to this division shall be public information and shall be released to the public.

130520. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

~~130521. (a) The department shall execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.~~

~~(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer patient assistance program.~~

~~(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.~~

~~(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.~~

~~(d) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:~~

~~(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.~~

~~(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.~~

~~(e) The California Rx Plus Discount Card issued pursuant to subdivision (c) of Section 130506 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a health benefit card.~~

130522. The department shall seek a determination from the federal Centers for Medicare and Medicaid Services that the program established pursuant to this division complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from the Medicaid best price requirement.

130523. (a) The department shall deposit all payments the department receives pursuant to this division into the California Rx Plus Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the department

without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130517 and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, the fund shall also contain any interest accrued on moneys in the fund.

~~SEC. 2. The sum of five million dollars ($5,000,000) is hereby transferred from the General Fund to the California Rx Plus Program Fund, to fund the cost of implementing the California Rx Plus State Pharmacy Assistance Program established pursuant to Division 112 (commencing with Section 130500) of the Health and Safety Code.~~

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 75 **VERSION: AMENDED APRIL 5, 2005**

AUTHOR: FROMMER **SPONSOR: FROMMER**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICAL ASSISTANCE PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California Rx Plus State Pharmacy Assistance Program (Program) within DHS. (H&S 130501 Added)

2. Defines the terms: Program, Department (DHS), fund (California Rx Plus Program Fund), program, manufacturer (drug manufacturer), resident, and qualified resident. (H&S 130500 Added)

3. Establishes the criteria for a qualified resident as:

   a. A resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines. (2005 - $38,280 for an individual and $77,400 for a family of four)

   b. A family that incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal fifteen percent or more of family income. (H&S 130500 Added)

4. Allows an individual enrolled in Medicare to participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare. (H&S 130505 Added)

5. Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. Requires DHS to coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. (H&S 130515 Added)

6. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program and to seek rebates equal to or greater then Medi-Cal rebates. (H&S 130518 Added)

7. Requires that all of the drug rebates negotiated will be used to reduce the cost of drugs purchased by participants in the program. (H&S 130518 Added)

8. Establishes the California Rx Plus Program Fund, but does not appropriate funds to implement the program. (H&S 130523 Added)

9. Makes it a misdemeanor to falsify information to gain access to the program. Additionally, it bars a person for one year from the program if the person falsifies information to gain access to the program. (H&S 130506 Added)

Comment:

1) Author's Intent. The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation. AB 74 (Gordon) California Rx Prescription Drug Hotline. This measure would require DHS to establish a drug hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

AB 73 (Frommer) Safe and Affordable Drug Importation from International Pharmacies, would require DHS to set up a web site that would provide information on importing drugs from international pharmacies.

AB 76 (Frommer) Office of Pharmaceutical Purchasing. This measure would instead establish within the California Health and Human Services Agency, the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies. The bill would authorize the office to conduct specified activates in order to negotiate the lowest prices possible for prescription drugs.

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians.

5) History.

2005

Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 2.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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BILL ANALYSIS
AB 75

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 75 (Frommer) - As Amended: April 5, 2005

SUBJECT : Pharmaceutical Assistance Program.

SUMMARY : Establishes the California Rx Plus State Pharmacy Assistance Program, to be administered by the Department of Health Services (DHS). Specifically, this bill :

1)Establishes the California Rx Plus State Pharmacy Assistance Program (Program), administered by DHS, and authorizes DHS to negotiate drug rebate agreements with drug manufacturers.

2)Authorizes any licensed pharmacy or drug manufacturer to provide services under the program.

3)Limits Program eligibility to qualified residents of California who do not have outpatient prescription drug coverage under any program funded in whole or part by the federal government except that a qualified resident enrolled in Medicare may participate in the program to the extent allowed by federal law.

4)Defines qualified resident to mean either of the following:

a) A resident of California who has a family income equal to or less than 400% of the federal poverty guidelines (FPL); or,

b) A resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal 15 percent or more of family income.

5)Specifies application procedures. Imposes penalties for intentionally making false statements on the application.

6)Requires DHS to execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

7)Requires DHS to develop a system, as specified, to provide a Program participant with the best discounts on prescription

drugs that are available to the participant through the Program or through a drug manufacturer patient assistance program.

8)Requires drug manufacturers to report annually to DHS regarding the utilization of drug company assistance programs.

9)Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in the Program.

10) Requires the amount a participant pays for a drug through the Program to be equal to the participating pharmacies usual and customary charge, or contract rate as specified, less a Program discount, as specified.

11) Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the Program. Requires DHS to seek rebate amounts equal to or greater than the Medi-Cal rebate, as specified. Requires various provisions in rebate agreements.

12) Permits DHS to limit the number of drugs available through the Program to obtain the most favorable discounts.

13) Requires all drug rebates negotiated pursuant to this bill to be used to reduce the cost of drugs purchased by Program participants.

14) Permits DHS to require Medi-Cal prior authorization for any drug of a manufacturer that does not agree to provide rebates to the Program, to the extent DHS determines it is appropriate to do in order to encourage manufacturer participation in the Program, and to the extent permitted by federal law, and subject to any necessary federal approvals or waivers.

15) Requires the names of manufacturers that do and do not agree to Program rebates to be public information.

16) Exempts Program contracts from the Public Records Act.

17) Requires DHS to seek a determination from the federal Centers for Medicare and Medicaid Services that the program established pursuant to this bill complies with the requirements for a state pharmaceutical assistance program and that discounts provided under the program are exempt from the Medicaid best price requirement.

18) Requires DHS to deposit all payments received pursuant to this bill into the California Rx Plus Program Fund to be

established in the State Treasury. States this fund is continuously appropriated and that no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

EXISTING LAW authorizes DHS to enter into contracts with drug manufacturers that provide rebates to the State and allow manufacturers' drugs to be placed on the Medi-Cal contract drug list.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill is needed to help Californians cope with the rising cost of prescription drugs by creating a drug discount card program for state residents. The author states that despite the skyrocketing cost of drugs, to date the state has done little, compared to other states, to help residents afford their medication.

2)BACKGROUND . Prices for prescription drugs have risen sharply in recent years, causing hardship for Californians. A 2004 study by Families USA found that the prices of the top 30 brand-name drugs dispensed to seniors have increased by nearly 22 percent in just three years. Between 2001 and 2004 the prices of these 30 drugs rose by 3.6 times the rate of inflation. In 2003 alone, the price of these drugs shot up at a rate more than four times that of overall inflation, placing increasing stress on the pocketbooks of many Californians dependent on these drugs for good health. A recent AARP study showed that prices for the 197 brand name drugs most commonly used by seniors continued to rise at a rate more than three times greater than inflation in 2004. As a result of these trends, the amount that Americans spend out of pocket on prescription drugs has risen dramatically in recent years: in 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15.3% over the previous year. In 2002, the annual increase in out-of-pocket spending for Americans was greater than the total increase in out-of-pocket spending for all other kinds of health care combined.

Californians without drug coverage can suffer adverse health effects by not taking all of their prescribed medications. A recent survey found that 37% of the uninsured said they did not fill a prescription because of cost, compared to 13% of the insured. A study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of

drugs by over 20% and experienced higher rates of emergency room visits and hospital stays.

3)STATE PHARMACY ASSISTANCE PROGRAMS . State Pharmacy Assistance Programs (SPAPs) are state-sponsored programs that generally provide selected populations with increased access to prescription drugs. As of March 2005 at least 39 states had established or authorized some type of program, to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Currently, 32 state programs are in operation. Most programs utilize state funds to subsidize a portion of an individual's drug costs, but an increasing number use discounts or bulk purchasing approaches.

Though most SPAPs target low-income individuals who are not eligible for Medicaid, many states have expanded their programs to serve individuals with higher incomes as well. All states provide coverage to those aged 65 and older, and half of the programs cover individuals with disabilities under age 65. Eligibility levels range from 100% FPL ($9,310 for an individual in 2004) in Arkansas and Louisiana to 500% FPL in Massachusetts ($46,550 for an individual in 2004). A few states have moved toward offering the benefits regardless of income, adjusting cost sharing requirements accordingly. In addition, a few programs have adjusted eligibility limits for individuals who have prescription drug expenses that are considered "catastrophic" (ranging from 3% to 40% of income).

4)PHARMACY ASSISTANCE PROGRAMS IN CALIFORNIA . The Legislature has enacted two discount programs in recent years to help Medicare beneficiaries cope with high drug costs. SB 393 (Speier), Chapter 946, Statutes of 1999, requires retail pharmacies to sell drugs to elderly and disabled persons on Medicare at a discount price that is just above the Medi-Cal price. SB 696 (Speier), Chapter 693, Statutes of 2001, established the Golden Bear Pharmacy Assistance Program to provide deeper discounts to Medicare recipients through negotiated voluntary rebates with drug manufacturers. However, in 2004 DHS ended its efforts to implement the program because of administrative problems passing rebates along to consumers and because few manufacturers had been willing to provide these rebates. Some drug manufacturers have patient assistance programs which offer prescription drugs at discounted prices or at no charge to qualifying patients. According to PhRMA, 244,000 Californians received industry sponsored assistance in 2002.

5)GOVERNOR'S SPAP PROPOSAL . The Governor has proposed a SPAP somewhat similar to this bill. The Governor's proposal was

initially offered as amendments to several legislative measures last year, but was not adopted. It is now contained in SB 19 (Ortiz). Under SB 19, uninsured California residents in families with income up to 300% FPL would be eligible to enroll. Pharmacists who voluntarily choose to participate would assist individuals in applying for discount cards and must sell prescription drugs at agreed-upon discounts. Drug manufacturers could participate in the program if they voluntarily agreed to provide rebates to the state. As in this bill, SB 19 would integrate the SPAP with private consumer discount programs and one discount card would access all participating programs. In a related effort, drug makers have pledged to spend $10 million over two years to publicize and fund toll-free telephone lines and Internet web sites to create a "single point of entry" for discounted drugs for Californians. Recently drug makers launched a national website, "helpingpatients.org," which has a California version, "rxhelpforca.org." These websites act as "gateways" to various drug discount programs.

In a February 2005 evaluation of SB 19, the Legislative Analysts Office (LAO) recommended that the Legislature try the SB 19 approach for voluntary rebates first, but direct DHS in advance to move forward with the type of approach included in this bill (leveraging the Medi-Cal program) if the Governor's program should fail to achieve its goals. To accomplish this the LAO proposes a detailed trigger mechanism.

This bill and SB 19 have many similarities, however this bill would extend eligibility, without regard to whether an individual has private insurance, to individuals with family incomes up to 400% FPL, and to families with incomes above 400% FPL if the family has unreimbursed drug expenses that equal 5% or more of family income or if total unreimbursed medical expenses equal 15% or more of family income. This bill also permits DHS to require prior authorization in the Medi-Cal program for any drug of a manufacturer that does not agree to provide rebates to the SPAP and requires the names of manufacturers that do and do not enter into rebate agreements with the SPAP to be public information.

6)SUPPORT . Supporters argue that Californians at all income levels are adversely affected by the high price of prescription drugs. Supporters argue that this bill is necessary because it includes critical provisions for the success of a discount card program, including utilizing Medicaid best price as a benchmark for discounts, including a "hammer" (Medi-Cal prior authorization) if drug companies refuse to offer adequate discounts, and including eligibility for residents with high medical bills.

7)OPPOSITION . Opponents specifically note their opposition to the Medi-Cal prior authorization provision of this bill, arguing this provision hurts Medi-Cal beneficiaries and is unlikely to be approved by the federal government. Opponents state that the federal government has not approved any SPAPs with eligibility levels above 200% FPL that leverage Medicaid. Opponents also argue that permitting DHS to limit the number of drugs available under the SPAP in order to obtain better prices will unfairly prevent access of SPAP enrollees to all drugs.

8)SUPPORT IF AMENDED . NAMI California has a support if amended position. NAMI asks for clarification of the income standards in determining eligibility for the program.

9)PREVIOUS LEGISLATION . SB 393 (Speier), Chapter 946, Statutes of 1999 and SB 696 (Speier), Chapter 696, Statutes of 2001 established drug discount programs to benefit Medicare beneficiaries. Both bills are discussed more fully above.

10)RELATED LEGISLATION . SB 19 (Ortiz), discussed above, is currently before the Senate Health Committee. In addition, a number of ballot initiatives to establish pharmaceutical discount programs are currently being circulated.

11)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

12)QUESTIONS . Should this bill more specifically define "income" especially for purposes of determining if a family's drug or medical expenses exceeds a specific percentage of "family income?" Should this bill include a continuing appropriation, as it currently does?

REGISTERED SUPPORT / OPPOSITION :

Support

AIDS Healthcare Foundation
Alzheimer's Association
American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Federation of Labor
California Federation of Teachers
California Labor Federation
California Nurses Association
California Public Interest Research Group
Consumers Union
Health Access California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union
One individual

Opposition

BIOCOM
California Chamber of Commerce
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Wyeth Pharmaceuticals

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

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AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 76

Introduced by Assembly Members Frommer and Chan
(Coauthors: Assembly Members ~~Bass, Evans, Gordon, Koretz, Nava, and Pavley~~ *Baca, Bass, Berg, Cohn, Coto, De La Torre, Evans, Goldberg, Gordon, Hancock, Klehs, Koretz, Leno, Levine, Lieber, Nava, Pavley, Ridley-Thomas, Ruskin, and Torrico*)

January 3, 2005

An act to amend Section 12803 of, to add Part 5.4 (commencing with Section 14570) to, and to repeal Chapter 12 (commencing with Section 14977) of Part 5.5 of, Division 3 of Title 1 of, the Government Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 76, as amended, Frommer. Office of Pharmaceutical Purchasing.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. Existing law requires 4 state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. Existing law grants the Department of General Services authority with respect to contracting with a pharmaceutical benefits manager or other entity and exploring additional strategies for managing drug costs.

This bill would repeal these provisions. The bill would instead establish within the California Health and Human Services Agency

the Office of Pharmaceutical Purchasing with authority and duties to purchase prescription drugs for state agencies similar to that granted to the Department of General Services under the above-described provisions. The bill would also, however, require the office to be the purchasing agent for ~~additional state entities~~ *the California State University and any other state agency as directed by the Governor, would add to those entities that may elect to participate in the purchasing program,* and ~~the bill~~ would authorize the office to conduct specified ~~activites~~ *activities* in order to negotiate the lowest prices possible for prescription drugs. The bill would require the office, on or before February 1, 2007, *and annually thereafter,* to submit a report containing specified information to certain committees of the Legislature regarding the program.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 12803 of the Government Code is amended to read:

12803. (a) The California Health and Human Services Agency consists of the following departments: Health Services; Mental Health; Developmental Services; Social Services; Alcohol and Drug Abuse; Aging; Rehabilitation; and Community Services and Development.

(b) The agency also includes the Office of Statewide Health Planning and Development and the State Council on Developmental Disabilities.

(c) The Department of Child Support Services is hereby created within the agency commencing January 1, 2000, and shall be the single organizational unit designated as the state's Title IV-D agency with the responsibility for administering the state plan and providing services relating to the establishment of paternity or the establishment, modification, or enforcement of child support obligations as required by Section 654 of Title 42 of the United States Code. State plan functions shall be performed by other agencies as required by law, by delegation of the department, or by cooperative agreements.

(d) The Office of Pharmaceutical Purchasing is hereby established within the agency and shall purchase prescription

drugs for state agencies pursuant to Part 5.4 (commencing with Section 14570).

SEC. 2. Part 5.4 (commencing with Section 14570) is added to Division 3 of Title 1 of the Government Code, to read:

PART 5.4. OFFICE OF PHARMACEUTICAL PURCHASING

14570. As used in this part, "office" means the Office of Pharmaceutical Purchasing within the California Health and Human Services Agency.

14571. (a) Notwithstanding any other provision of law, the office may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law. Contracts entered into pursuant to this part may include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices.

(b) Contracts under this part shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

~~(c) To the extent permitted by federal law, and subject to any necessary federal approvals or waivers, the State Department of~~

(c) The State Department of Health Services may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) for any drug of a manufacturer that does not agree to provide rebates to the office for prescription drugs purchased under this part *to the extent the department determines it is appropriate to do so in order to encourage manufacturer participation, and to the extent permitted by federal law and subject to any necessary federal approvals or waivers. It is the intent of the Legislature to limit any rebates that are obtained as a result of the establishment of a prior authorization requirement in Medi-Cal to drugs prescribed to financially needy individuals who, through the use of these prescribed drugs, would improve their health status and become less likely to enroll in the Medi-Cal program.*

14572. (a) The office shall be the purchasing agent for prescription drugs for all of the following state entities:

~~(1) State Department of Health Services.~~
~~(2)~~
(1) Department of Corrections.
~~(3)~~
(2) State Department of Mental Health.
~~(4)~~
(3) Department of the Youth Authority.
~~(5)~~
(4) State Department of Developmental Services.
~~(6) Department of Veterans Affairs.~~
~~(7)~~
(5) California State University.
~~(8)~~
(6) Any other state agency as directed by the Governor.

(b) Any state, district, county, city, municipal, *school district, joint powers agreement or trust that administers or pays public employee benefits,* or public agency governmental entity, other than a state entity specified in subdivision (a), may elect to participate in the coordinated purchasing program.

14573. *(a) The office shall work with the University of California to identify opportunities for consolidating the drug purchases made by both agencies in order to lower the state's costs for purchasing prescription drugs. It is the intent of the Legislature that the University of California cooperate with the office in these efforts.*

(b) The office shall develop an annual work plan that provides a comprehensive approach to reducing the state's procurement costs for prescription drugs. The work plan shall detail the office's annual activities and the estimated savings that these activities are expected to achieve. The office shall use the work plan when reporting to the Legislature on estimated and achieved savings resulting from the office's activities.

(c) The office shall participate in at least one independent group that develops information on the relative effectiveness of prescription drugs.

(d) (1) It is the intent of the Legislature that the state provide parolee medications in the most cost-effective manner. In deciding how to purchase parolee medications, the office shall consider, but not be limited to, all of the following:

(A) Contracting with a pharmacy benefits manager.

(B) Purchasing medications under pharmacy contracts used for prison inmates.

(C) To the extent feasible, requiring prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) to obtain drug discounts for the parolee population.

(2) The office shall compare the cost of these options and choose the lowest cost option.

14574. (a) In order to negotiate the lowest prices possible for prescription drugs for purposes of this part, the office may do all of the following:

(1) Establish a formulary or formularies for state programs in consultation with the affected agencies.

(2) Pursue all opportunities for the state to achieve savings through the federal 340B program, as established under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b), including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for individuals receiving presciption drugs through programs in departments described in Section 14572.

(3) Develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the program authorized under Section 340B of the Public Health Service Act (42 U.S.C. Sec. 256b).

(b) The office, in consultation with the agencies listed in subdivision (a) of Section 14572, may investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

~~14574.~~

14575. The office may appoint and contract with a pharmaceutical benefits manager or other entity for purposes of the prescription drugs purchased under this part. The pharmaceutical benefits manager or other entity may do all of the following:

(a) Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

(b) Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

(c) Act as a consultant to the office.

~~14575. The department~~

14576. The office may explore additional strategies for managing the increasing costs of prescription drugs, including, but not limited to, all of the following:

(a) Coordinating programs offered by pharmaceutical manufacturers that provide prescription drugs for free or at reduced prices.

(b) Studying the feasibility and appropriateness of including in the bulk purchasing programs entities in the private sector, including employers, providers, and individual consumers.

(c) Implementing other strategies, as permitted under state and federal law, aimed at managing escalating prescription drug prices.

~~14576.~~

(d) It is the intent of the Legislature that the office, State Department of Health Services, University of California, and Public Employees' Retirement System share information on a regular basis on drug purchasing activities.

14577. On or before February 1, 2007, *and annually thereafter,* the office shall submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been or will be undertaken pursuant to this part. The report shall include, but not be limited to, all of the following:

(a) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14571, including any discounts, rebates, or refunds obtained.

(b) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to subdivision (b) of Section 14572.

(c) Other options and strategies that have been or will be implemented pursuant to Sections 14573 and 14575.

(d) Estimated costs and savings attributable to activities that have been or will be undertaken pursuant to this part.

(e) The identification of the collaborative activities that the office, State Department of Health Services, University of California, and Public Employees' Retirement System conducted in the past 12 months to reduce the cost of drug purchasing by the state and the savings attributable to those activities.

(f) The identification of opportunities to consolidate drug purchases with the University of California.

SEC. 3. Chapter 12 (commencing with Section 14977) of Part 5.5 of Division 3 of Title 1 of the Government Code is repealed.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 76 **VERSION: AMENDED APRIL 5, 2005**

AUTHOR: FROMMER et. al. **SPONSOR: FROMMER**

RECOMMENDED POSITION: NO POSITION

SUBJECT: OFFICE OF PHARMACEUTICAL PURCHASING

Existing Law:

1) Authorizes the Department of General Services (DGS) to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. (Govt Code 14977-14981)

2) Requires four state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. (Govt Code 14977-14981)

This Bill:

1) Repeals these provisions authorizing DGS's drug purchasing program. (Govt Code 14977-14981 Repealed)

2) Creates the Office of Pharmaceutical Purchasing (Office) within California Health and Human Services Agency to purchase prescription drugs for the following entities:

a. California Department of Corrections (CDC)

b. Department of Mental Health (DMH)

c. California Youth Authority (CYA)

d. Department of Developmental Services (DDS)

e. Department of Veterans Affairs

f. California State University (CSU)

g. Any other state agency as directed by the Governor.

h. Any state, district, county, city, municipal, school district, joint powers agreement or trust that administers or pays public employee benefits, or public agency governmental entity that may elect to participate in the coordinated purchasing program. (Govt Code 12803 Amended, 14572 Added)

3) Requires the Office to work with the University of California (UC) to identify opportunities for consolidating the drug purchases made by both agencies in order to lower the state's costs for purchasing prescription drugs. (Govt Code 14573 Added)

4) Authorizes the office to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The office may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar, as permissible under federal law.

(Govt Code 14571 Added)

5) Authorizes the office to appoint and contract with a pharmaceutical benefits manager (PBM) or other entity to do all of the following:

a. Negotiate price discounts, rebates, or other options that achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

b. Purchase prescription drugs for participating state, district, county, or municipal governmental entities.

c. Act as a consultant to the office. (Govt Code 14575 Added)

6) Requires the office, on or before February 1, 2007, to submit a report to the Legislature on activities that have been or will be undertaken. The report would include the following:

a. The number and a description of contracts entered into with manufacturers and suppliers of drugs including any discounts, rebates, or refunds obtained.

b. The number and a description of entities that elect to participate in the coordinated purchasing program.

c. Other options and strategies that have been or will be implemented pursuant to receive the lowest cost drugs.

d. Estimated costs and savings attributable to activities that have been or will be undertaken by the office.

e. Identify the collaborative activities that the office, State Department of Health Services, University of California, and Public Employees' Retirement System conducted in the past 12 months to reduce the cost of drug purchasing by the state and the savings attributable to those activities.

(Govt Code 14577 Added)

Comment:

1) Author's Intent. The author's intent is to implement drug-purchasing recommendations made by the California Performance Review (CPR). CPR estimates that its drug purchasing proposals would result in $75 million in annual state savings.

2) Current DGS Drug Purchasing Program. DGS is responsible for procuring drugs for CDC DMH, DDS, CYA, and CSU's student health centers. DGS contracts with a vendor, McKesson Corporation, to process departmental drug orders and then distribute those orders to the departments. McKesson acquires the drugs through 1) competitively procured state contracts for generic drugs, 2) negotiated state contracts for brand-name drugs, or 3) the Massachusetts Alliance, a GPO consisting of both public and private agencies. For drugs that are not available through these methods, McKesson acquires the drugs at discounted wholesale prices.

3) LAO Report. A February 2005 Legislative Analyst Office (LAO) Report, Lowering the State's Costs for Prescription Drugs, examines how the state purchases drugs for its program recipients. The LAO report was critical of many elements in CPR's drug purchasing proposal, which are also found in AB 76. Specifically, the LAO found:

a. The use of a PBM would not benefit the state since the state already has established a drug formulary, authority to negotiate drug rebates, and usually does not purchase drugs from private pharmacies.

b. There is a limited need for a drug purchasing office given that the creation of a new office could be costly, create organizational difficulties, and provide little strategic advantage to the state over the current arrangement in which procurement duties are already largely concentrated.

Overall the LAO found the state's various drug-purchasing programs could take specific actions to improve on getting the lowest price possible for prescription drugs. Legislation would be required to implement most of the actions recommended by the LAO.

4) April 5, 2005 Amendments. The April 5th amendments 1) deleted the Department of Veterans Affairs from the list of departments included in the pharmaceutical purchasing program, 2) required the office to coordinate with the UC to identify opportunities for consolidating the drug purchases, and 3) made other less substantive amendments to the bill.

5) History.

Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 3.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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BILL ANALYSIS
AB 76

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 76 (Frommer) - As Amended: April 5, 2005

SUBJECT : Office of Pharmaceutical Purchasing.

SUMMARY : Establishes the Office of Pharmaceutical Purchasing (OPP) in the Health and Human Services Agency (HHSA) to purchase prescription drugs for state agencies. Specifically, this bill :

1)Establishes OPP in HHSA. Permits OPP to enter into contracts with manufacturers and suppliers of prescription drugs. Permits OPP to obtain from those manufacturers and suppliers, discounts, rebates, or refunds as permitted under federal law. Exempts OPP contracts from the Public Records Act.

2)Permits DHS to require prior authorization in the Medi-Cal program for any drug of a manufacturer that does not agree to provide rebates to OPP to the extent DHS determines it is appropriate to do so in order to encourage manufacturer participation, and to the extent permitted by federal law and subject to any necessary federal approvals or waivers. States legislative intent to limit any rebates that are obtained as a result of the establishment of a prior authorization requirement in Medi-Cal to drugs prescribed to financially needy individuals who, through the use of these prescribed drugs, would improve their health status and become less likely to enroll in the Medi-Cal program.

3)Requires OPP to be the purchasing agent for prescription drugs for all of the following:

a) Department of Corrections;
b) Department of Mental Health;
c) Department of the Youth Authority;
d) Department of Developmental Services;
e) California State University; and,
f) Any other state agency as directed by the Governor.

4)Permits any state, district, county, city, municipal, school district, joint powers agreement or trust that administers or pays public employee benefits, or public agency governmental entity to participate in OPP's coordinated purchasing program.

5)Permits OPP to work with the University of California (UC) to

identify opportunities for consolidating the drug purchases made by both agencies in order to lower the state's costs for purchasing prescription drugs.

6)Requires OPP to participate in at least one independent group that develops information on the relative effectiveness of prescription drugs.

7)States legislative intent for the state to provide parolee medications in the most cost-effective manner. Requires OPP to compare various options for purchasing parolee medications and to choose the lowest cost option.

8)Permits OPP to do all of the following in order to negotiate the lowest prices possible for prescription drugs:

a) Establish a formulary or formularies in consultation with the affected agencies;

b) Pursue all opportunities for the state to achieve savings using Section 340B of the Public Health Service Act (340B program), including the development of cooperative agreements with entities covered under the 340B program that increase access to 340B program prices for individuals receiving prescription drugs through programs in entities listed in #3) and #4) above; and,

c) Develop an outreach program to ensure that hospitals, clinics, and other eligible entities participate in the 340B program.

9)Permits OPP, in consultation with the entities listed in #3) above to investigate and implement other options and strategies to achieve the greatest savings on prescription drugs with prescription drug manufacturers and wholesalers.

10) Permits OPP to appoint and contract with a pharmaceutical benefits manager (PBM) or other similar entity as specified and to explore additional strategies for managing the increasing costs of prescription drugs.

11) States legislative intent for OPP, DHS, UC, and the Public Employees' Retirement System (CalPERS) to share drug purchasing information.

12) Requires OPP to develop an annual work plan and to submit an annual report to the Legislature.

13) Repeals provisions of the Government Code authorizing DGS to negotiate contracts for prescriptions drugs for specified state agencies and other entities.

EXISTING LAW :

1)Authorizes the DGS to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of prescription drugs to obtain discounts, rebates, or refunds as permitted by federal law.

2)Requires four state agencies to participate in the program authorized by #1) above and authorizes other public entities to elect to participate in the program.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill will enable the state to take better advantage of its bargaining power to hold down the cost of prescription drugs. The author points out that both the Legislative Analyst's Office (LAO) and the California Performance Review found major deficiencies in the way the state is currently purchasing prescription drugs and recommended a number of changes, which are incorporated in this bill. The author believes the state can save millions of dollars in programs that buy drugs and that these savings can be redirected to maintain health, education, transportation and other programs that are threatened by the state's current budget deficit.

Specifically, the author believes that consolidating DGS' purchasing into HHSA will address a number of the problems identified in the LAO report. For example, consolidation into an Agency experienced in purchasing pharmaceuticals and health care services should allow state programs to take advantage of better leadership for drug purchasing. The experience of DHS' staff would help OPP staff develop a work plan for drug buying and accelerate contract negotiation. Consolidation would allow closer coordination of pharmaceutical negotiations between DHS and the programs that currently buy drugs through DGS. The author notes that, although federal law and confidentiality rules may not permit Medi-Cal to jointly negotiate with other programs directly with drug makers, there are many ways that DHS could share information and expertise to benefit purchasing for other programs. This coordination and information sharing would be facilitated by location in the same Agency, with the Agency Secretary and staff ensuring that the different drug purchasing programs work together.

2)BACKGROUND . The state of California has seen its costs for prescription drugs rise rapidly in recent years. According to the Legislative Analysts Office, state agencies purchase about

$4.2 billion in prescription and nonprescription drugs annually. Prescription drug costs for the taxpayer financed Medi-Cal fee-for-service program (after current rebates) was $2.4 billion in 2001-02. According to the Department of Health Services (DHS) it is projected to reach $3.5 billion 2004-05. Medi-Cal managed care spends hundreds of millions of dollars more each year. According to a 2002 Bureau of State Audits review, the five state agencies that most frequently purchase prescription drugs experienced an annual average increase of 34 percent in their drug costs from 1996 to 2001. The overall cost of drug expenditures for these five agencies rose from $41.6 million in 1996-97 to $153.6 million in 2002-03. For the Department of Corrections (CDC), the average cost of pharmaceuticals has risen from $197 per inmate in 1996-97 to $770 per inmate in 2001-02. CDC now pays more than $125 million annually for prescription drugs.

3)CALIFORNIA PERFORMANCE REVIEW . The California Performance Review (CPR), initiated by the Governor, called for the state to take immediate steps to purchase drugs in a more coordinated, unified fashion. The CPR noted that several state agencies purchase drugs independently of each other, weakening the state's ability to bargain aggressively for better prices. The CPR said that:

> Although the state's purchasing power should equate to a strong market position and lower drug prices, this is not the case. Several of the state agencies purchasing drugs do so independently of each other and thus segment themselves into smaller markets? Although each state entity may do an admirable job of negotiating drug prices, this practice weakens their market position and results in higher drug costs. Working together to combine drug purchases would significantly increase their volume purchasing power thus establishing a stronger market position leading to lower drug costs.

The CPR recommended that the Governor and Legislature should work together to create a new Central Pharmaceutical Office that should be responsible for the procurement and management of all pharmaceutical programs. The CPR also recommended that this office should have the authority to establish cooperative relationships with local governments, other state entities and drug manufacturers in order to maximize the state's purchasing power. Finally, the CPR recommended that the Department of General Services (DGS), or its successor, enter into a contract with a Pharmacy Benefits Manager to administer the state's drug purchasing program.

In addition, the CPR also showed that safety net providers are

able to obtain prescription drugs for their patients at a 50 % discount off of retail prices through the federal 340B program. The federal 340B program permits various "covered entities," mostly safety net health care providers like community clinics and disproportionate-share public and private hospitals, to obtain steeply-discounted drugs for patients of those providers. Utilizing 340B prices for state programs could save the state millions of dollars through the use of cooperative agreements between the state and safety net providers that would allow the state to access these prices. This bill would direct the new Office of Pharmaceutical Purchasing to aggressively explore opportunities for savings through these cooperative agreements.

4)LEGISLATIVE ANALYSTS OFFICE . A recent LAO report, Lowering the State's Costs for Prescription Drugs , identified a range of deficiencies in the state's procurement of prescription drugs that lead to the state paying higher drug costs than necessary. For example, the report found that the state does not leverage Medi-Cal's purchasing power for all state programs. The report notes that recent court decisions have opened the way for states, under certain circumstances, to use their Medicaid programs as a means to obtain lower drug prices for non-Medicaid populations. States may be able to do this as long as their actions would further the goals of Medicaid, such as providing assistance to people who might otherwise end up on the Medicaid rolls. The report notes that the state would have to receive prior federal approval for such actions.

The report also found that the DGS is not providing sufficient leadership in drug procurement. Specifically, the report found that DGS has no comprehensive work plan or strategy for aggressively lowering drug costs; DGS purchases almost half of its drugs without contracts, which results in the state paying higher prices; and DGS does not participate in independent groups that review the comparative effectiveness of similar drugs. The report found that there is insufficient collaboration among state agencies in their drug purchasing: for example, the LAO says that DGS officials have little regular interaction with the branch of DHS that negotiates with manufacturers for drugs for Medi-Cal recipients.

The LAO report recommended a variety of changes to state drug purchasing. The LAO recommended that the Legislature should:

a) Enact a statute to leverage Medi-Cal to get rebates for other state programs;
b) Require collaboration and information sharing on drug purchasing among DGS, DHS, UC and PERS;
c) Direct DGS and UC to identify consolidated purchasing opportunities;

d) Require DGS to develop annual work plan for purchasing drugs;
e) Require DGS participation in evidence-based drug reviews by outside entities;
f) Direct DGS and Corrections to compare different strategies to lower parolee drug costs;
g) Require Corrections to continue pharmacy improvements;
h) Increase DGS staff to create more drug contracts;
i) Direct DHS to modify formulary regulations to permit DMH and DDS to have one formulary committee to serve all of an agency's facilities, rather than require each facility to have a formulary;
j) Direct DDS, DMH and DADP to modify their reimbursement systems to account separately for purchases so as to get Medicaid prices for certain drugs; and,
aa) Ask Congress to allow states to use Federal Supply Schedule prices for drugs bought for state mental hospitals and developmental centers.

The LAO estimated that, in the long term, leveraging Medi-Cal's preferred drug list and directing UC and DGS to identify joint drug purchases could save the state millions of dollars annually. The LAO said that in the short-term, a number of its recommendations for collaboration and planning could result in unknown savings.

5)OTHER STATES . Other states, too, have taken steps in recent years to aggregate the purchasing power of state programs. For example, in 2003 the Governor of Illinois created a Special Advocate for Prescription Drugs to provide strategic coordination of prescription drug contracts and programs by a central state purchasing agent. In late 2004 the Governor of West Virginia followed suit, creating a cabinet-level Pharmaceutical Advocate to direct state government procurement of prescription drugs. The state of Maine, in its recently-enacted 2005-06 budget, established a Pharmaceutical Cost Management Council to jointly purchase drugs for a number of state program, and Massachusetts and Pennsylvania also have centralized purchasing initiatives underway.

6)SUPPORT . Supporters argue this bill is needed to effectively coordinate prescription drug purchasing by various state agencies. Despite recent legislation to consolidate purchasing in the hands of DGS, the state continues to overpay for prescription drugs according to both the LAO and CPR. Supporters believe that the monies wasted on separate buying agreements could be better used to help benefit Californians through other services such as education, law enforcement, and additional health related services.

7)OPPOSITION . Opponents emphasize two points in opposing this

bill: first, that this bill is premature and unnecessary because SB 1315, Chapter 483, Statutes of 2002, enacted in 2002, gave similar powers to DGS; second, that by leveraging the Medi-Cal program, this bill will jeopardize the access of Medi-Cal patients to needed medications. In addition opponents fear that this bill, by promoting formularies, will discourage research and development of new drugs.

8)CONCERN . The California Public Interest Research Group (CalPIRG), while strongly supporting the concept of prescription drug buying pools, expresses reservations about this bill as currently written. Before transferring the current drug buying program at DGS to HHSA, CalPIRG urges the author and committee to review the report to the Legislature required by SB 1315. However, the requirement for that report was repealed by AB 79.

9)PREVIOUS LEGISLATION . SB 1315 (Sher) permits DGS to enter into contracts on behalf of state and local agencies with manufacturers and suppliers of prescription drugs and permits these contracts to include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices. SB 1315 also required DGS to submit a report the Legislature regarding its effect by February 1, 2005. However, that requirement was repealed by AB 79 (Dutra), Chapter 409, Statutes of 2004. According to an LAO report released in February 2005, DGS had negotiated reduced prices for 4 classes of drugs since SB 1315 was enacted.

10)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

American Federation of State, County and Municipal Employees
California Alliance of Retired Americans
California Federation of Labor
Consumers Union
Health Access
Older Women's League of California
Senior Action Network
Service Employees Union International

Opposition

Biocom
California Chamber of Commerce
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Wyeth Pharmaceuticals

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

AMENDED IN ASSEMBLY APRIL 12, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 306

Introduced by Assembly Member Baca

February 9, 2005

~~An act relating to prescription drugs.~~ *An act to add Chapter 13 (commencing with Section 14985) to Part 5.5 of Division 3 of Title 2 of the Government Code, relating to prescription drugs, and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

AB 306, as amended, Baca. Purchasing pools for prescription drugs.

Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.

~~This bill would state the intent of the Legislature to enact legislation that would establish a prescription drug purchasing pool that would bring down prescription drug costs of many Californians by allowing employer health plans and the uninsured to join with state and local governments and school districts in the purchase of prescription drugs.~~

This bill would establish in the Department of General Services, the California Prescription Drug Program, to purchase prescription drugs or reimburse pharmacies for prescription drugs in order to

receive discounted prices and rebates, to make prescription drugs available at the lowest possible cost to individuals and entities participating in the program, and to maintain a list of prescription drugs recommended as the most effective prescription drugs available at the best possible prices. The bill would establish eligibility criteria for California residents to participate in the program and would require the department to establish procedures for nongovernmental, nonpublic entities to participate in the program on behalf of eligible California residents.

The bill would require the department, subject to funding, to implement the California Prescription Drug Program on or before July 1, 2006. The bill would require the department to appoint an administrator of the program and would establish the duties of that administrator. The bill would require the department, on or before June 1, 2006, to report to the Legislature on the department's preparations to implement the program.

The bill would also require the State Department of Health Services to develop and recommend to the Department of General Services a preferred drug list for use in the California Prescription Drug Program and would require the State Department of Health Services to conduct public hearings to develop the preferred drug list.

The bill would establish the California Prescription Drug Program Fund in the State Treasury, as a continuously appropriated fund, which would consist of all moneys appropriated to the fund in the annual Budget Act and moneys received by the department in the form of gifts, grants, bequests, endowments, or donations, to be used for the purposes of the bill.

The bill would appropriate an unspecified amount from the General Fund to the department to implement the program.

Vote: ~~majority~~ *2/3*. Appropriation: ~~no~~ *yes*. Fiscal committee: ~~no~~ *yes*. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. It is the intent of the Legislature to enact in subsequent amendments legislation that would establish a prescription drug purchasing pool that would bring down prescription drug costs of many Californians by allowing employer health plans and the uninsured to join with state and~~

~~local governments and school districts in the purchase of prescription drugs.~~

SECTION 1. Chapter 13 (commencing with Section 14985) is added to Part 5.5 of Division 3 of Title 2 of the Government Code, to read:

CHAPTER 13. CALIFORNIA PRESCRIPTION DRUG PROGRAM

14985. As used in this chapter, the following definitions shall apply:

(a) "Department" means the Department of General Services.

(b) "Pharmacy benefit manager" means an entity that, in addition to being a prescription drug claims processor, negotiates, and executes contracts with pharmacies, manages preferred drug lists, negotiates with prescription drug manufacturers, and serves as an intermediary between the California Prescription Drug Program, prescription drug manufacturers, and pharmacies.

(c) "Prescription drug claims processor" means an entity that processes and pays prescription drug claims, adjudicates pharmacy claims, transmits prescription drug prices and claims data between pharmacies and the California Prescription Drug Program, and processes related payments to pharmacies.

(d) "Program price" means the reimbursement rates and prescription drug prices established by the administrator of the California Prescription Drug Program.

14985.1. (a) The California Prescription Drug Program is established in the Department of General Services.

(b) Subject to available funding, the department shall implement this chapter on or before July 1, 2006.

14985.3. The California Prescription Drug Program shall have all of the following purposes:

(a) To purchase prescription drugs or reimburse pharmacies for prescription drugs in order to receive discounted prices and rebates.

(b) To make prescription drugs available at the lowest possible cost to individuals and entities participating in the program.

(c) To maintain a list of prescription drugs recommended as the most effective prescription drugs available at the best possible prices.

14985.5. The Director of General Services shall appoint an administrator of the California Prescription Drug Program. The administrator shall have all of the following duties:

(a) Negotiate price discounts and rebates on prescription drugs with prescription drug manufacturers.

(b) Purchase prescription drugs on behalf of individuals and entities that participate in the program.

(c) Contract with a prescription drug claims processor to adjudicate pharmacy claims and transmit program prices to pharmacies.

(d) Determine program prices and reimburse pharmacies for prescription drugs.

(e) Adopt and implement a preferred drug list for the program.

(f) Develop a system for allocating and distributing the operational costs of the program and any rebates obtained to participants of the program.

(g) Cooperate with other states or regional consortia in the bulk purchase of prescription drugs.

14985.7. (a) Residents of this state who meet all of the following criteria may participate in the program.

(1) Are more than ___ years of age.

(2) Have a gross annual income that does not exceed 185 percent of the federal poverty guidelines.

(3) Have not been covered under any private prescription drug benefit program for the previous six months.

(b) The department shall develop a procedure for nongovernmental, nonpublic entities to participate in the program, which shall ensure that only residents in the state that meet the requirements set forth in subdivision (a) receive benefits under the program.

14985.9. (a) The administrator may establish different reimbursement rates or prescription drug prices for pharmacies in rural areas to maintain statewide access to the program.

(b) The administrator shall establish the terms and conditions for a pharmacy to enroll in the program. A licensed pharmacy that is willing to accept the terms and conditions established by the administrator may apply to enroll in the program.

(c) The administrator shall contract with one or more entities to provide the functions of a prescription drug claims processor. The administrator may also contract with a pharmacy benefit manager to negotiate with prescription drug manufacturers on behalf of the administrator.

(d) Except as provided in subdivision (c), the administrator shall not do any of the following:

(1) Contract with a pharmacy benefit manager.

(2) Establish a state-managed wholesale or retail drug distribution or dispensing system.

(3) Require pharmacies to maintain or allocate separate inventories for prescription drugs dispensed through the program.

14985.11. (a) An individual described in subdivision (a) of Section 14985.7 may apply to participate in the California Prescription Drug Program. An individual shall apply annually on an application provided by the department. The department may charge individuals a nominal fee to participate in the program. The department shall issue a prescription drug identification card annually to participants in the program.

(b) An entity described in subdivision (b) of Section 14985.7 may apply to participate in the program in accordance with the procedures established by the department.

(c) The department shall provide a mechanism to calculate and transmit the program prices for prescription drugs to a pharmacy. The pharmacy shall charge the department a program price for a prescription drug.

(d) A pharmacy may charge individuals and entities participating in the program a professional fee established by the department.

(e) Prescription drug identification cards issued under this section shall contain the information necessary for proper claims adjudication or transmission of price data.

14985.13. The State Department of Health Services shall develop and recommend to the department a preferred drug list that identifies preferred choices of prescription drugs within therapeutic classes for particular diseases and conditions, including generic alternatives, for use in the California Prescription Drug Program. The State Department of Health Services shall conduct public hearings and use evidence-based

evaluations on the effectiveness of similar prescription drugs to develop the preferred drug list.

14985.15. (a) The Prescription Drug Purchasing Fund is hereby established in the State Treasury. The fund shall consist of moneys appropriated to the fund in the annual Budget Act and moneys received by the department in the form of gifts, grants, bequests, endowments, or donations.

(b) The moneys in the fund shall be continuously appropriated to the department and shall be expended to purchase prescription drugs, reimburse pharmacies for administering the California Prescription Drug Program, and reimburse the department for the costs of administering the California Prescription Drug Program, including contracted services costs, computer costs, professional dispensing fees paid to retail pharmacies, and other reasonable program costs. Interest earned on the fund shall be credits to the fund.

14985.17. The department shall adopt regulations to implement and administer this chapter. The regulations shall include, but shall not be limited to, establishing procedures for both of the following:

(a) Issuing prescription drug identification cards to individuals and entities that participate in the program.

(b) Enrolling pharmacies in the program.

14985.19. On or before June 1, 2006, the department shall report to the Legislature on the department's preparations to implement the California Prescription Drug Program, which shall include, but not be limited to, all of the following:

(a) The number of individuals and entities that the department expects to enroll in the program and the number of persons for whom the department expects to purchase prescription drugs.

(b) How the department expects the program to affect prescription drug prices for participants.

(c) The regulations proposed or adopted by the department to implement the program.

(d) The feasibility and advisability of expanding the program.

(e) A plan to expand the program if the department determines that expansion is feasible and advisable.

SEC. 2. The sum of _____ ($_____) is hereby appropriated from the General Fund to the Department of General Services for the purpose of carrying out the California Prescription Drug

Program pursuant to Chapter 13 (commencing with Section 14985) of Part 5.5 of Division 3 of Title 2 of the Government Code.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 306 **VERSION: AMENDED APRIL 12, 2005**

AUTHOR: BACA **SPONSOR: BACA**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA PRESCRIPTION DRUG PROGRAM

Existing Law:

1) Authorizes the Department of General Services (DGS) to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. (Govt Code 14977-14981)

2) Requires four state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. (Govt Code 14977-14981)

This Bill:

1) Establishes the California Prescription Drug Program (Program) within DGS, and, if funds are available, would require DGS to implement the program by July 1, 2006. (Govt. Code 14985.1 Added)

2) Requires the administrator of the Program to:

a. Negotiate price discounts and rebates on prescription drugs with prescription drug manufacturers.

b. Purchase prescription drugs on behalf of individuals and entities that participate in the program.

c. Contract with a prescription drug claims processor to adjudicate pharmacy claims and transmit program prices to pharmacies.

d. Determine program prices and reimburse pharmacies for prescription drugs.

e. Adopt and implement a preferred drug list for the program.

f. Develop a system for allocating and distributing the operational costs of the program and any rebates obtained to participants of the program.

g. Cooperate with other states or regional consortia in the bulk purchase of prescription drugs.

(Govt. Code 14985.5 Added)

3) Establishes minimum age and maximum income requirements for participation in the program; age, not specified; income of no more than185 percent of the federal poverty guidelines. (Govt. Code 14985.7 Added)

4) Requires DGS to develop a procedure for nongovernmental, nonpublic entities to participate in the program. (Govt. Code 14985.7 Added)

5) Allow the administrator to do the following:

a. Establish different reimbursement rates or prescription drug prices for pharmacies in rural areas to maintain statewide access to the program.

b. Establish the terms and conditions for a pharmacy to enroll in the program.

c. Contract with one or more entities to provide the functions of a prescription drug claims processor.

d. Contract with a pharmacy benefit manager to negotiate with prescription drug manufacturers on behalf of the administrator.

(Govt. Code 14985.9 Added)

6) Permits DGS to charge a nominal fee for participation in the program, and to issue prescription drug identification cards to participants in the program.
(Govt. Code 14985.11 Added)

7) Establishes the Prescription Drug Purchasing Fund in the State Treasury, with funding from the program being appropriated in the annual budget act.
(Govt. Code 14985.15 Added)

8) Requires DGS to adopt regulations to implement and administer the program.
(Govt. Code 14985.17 Added)

9) Requires DGS, on or before June 1, 2006, to report to the Legislature on the department's preparations to implement the program. (Govt. Code 14985.19 Added)

Comment:

1) Author's Intent. The author's intent is to use the purchasing power of state agencies to negotiate lower prices on prescription drugs for those most in need of assistance. The author is likely amend the age and income requirements for the program to 18 years or older and a maximum income of 300 percent of the federal poverty guidelines.

2) Oregon Legislation. AB 306 is modeled after Oregon legislation, SB 875 (2003), which created the Oregon Prescription Drug Program. The Oregon program has been up and running for one month, so there is no information available on the effectiveness of the program.

3) Amended on April 12, 2005. The introduced version of this bill was a spot bill stating the intent of the legislature to establish a prescription drug purchasing program.

4) Other Legislation.

AB 75 (Frommer) Pharmaceutical Assistance Program, would establish a prescription drug discount program for low-income state residents.

AB 76 (Frommer) Office of Pharmaceutical Purchasing, would place the responsibilities of several state agencies under a new state Office of Pharmaceutical Purchasing to purchase prescription drugs.

SB 19 (Oritz) California Rx Program, would establish the California Pharmacy Assistance Program (Cal Rx) under the oversight of DHS.

5) History.

2005	
Apr. 12	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 11	Referred to Coms. on HEALTH and B. & P.
Feb. 10	From printer. May be heard in committee March 12.
Feb. 9	Read first time. To print.

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AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 78

Introduced by Assembly Member Pavley
(Coauthors: Assembly Members Bass, Chan, Evans, Frommer, Gordon, and Koretz)

January 3, 2005

An act to add Division 113 (commencing with Section 150000) to the Health and Safety Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 78, as amended, Pavley. Pharmacy benefits management.

Existing law provides for the regulation of health care benefits.

This bill would define the term "pharmacy benefits management" as the administration or management of prescription drug benefits. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager's revenues ~~and its drug formularies, and to make specified disclosures to the public upon request~~. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts ~~and the provision of certain drugs~~. ~~The bill would impose certain requirements on the membership of a pharmacy and therapeutics committee for a pharmacy benefits manager. The bill would also require a pharmacy benefits manager to meet certain conditions before substituting a prescribed medication.~~

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Division 113 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 113. PHARMACY BENEFITS MANAGEMENT

150000. For purposes of this division, the following definitions shall apply:

(a) "Labeler" means any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(b) "Pharmacy benefits management" is the administration or management of prescription drug benefits. Pharmacy benefits management shall include all of the following: the procurement of prescription drugs at a negotiated rate for dispensation within this state, the processing of prescription drug claims, and the administration of payments related to prescription drug claims.

(c) "Pharmacy benefits manager" is any ~~person who~~ *entity that* performs pharmacy benefits management. The term does not include a health care service plan or health insurer if the health care service plan or health insurer offers or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered or provided by that health care service plan or health insurer, nor does the term include an affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a pharmacy benefits manager, as long as the services offered or provided by the related entity are offered or provided only to enrollees, subscribers, or insureds who are also covered by the health benefits offered or provided by that health care service plan or health insurer.

~~(d) "Prospective purchaser" is any person to whom a pharmacy benefits manager offers to provide pharmacy benefit management services.~~

~~(e)~~

(d) "Purchaser" is any ~~person who~~ *entity that* enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services.

~~150001. A pharmacy benefits manager shall disclose to the purchaser in writing all of the following:~~

~~(a) The aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the purchaser.~~

~~(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the purchaser. A therapeutic class shall include at least two drugs.~~

~~(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the purchaser. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.~~

~~(d) Any prescription drug utilization information related to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.~~

~~(e) Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.~~

~~(f) Any arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy~~

~~benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.~~

~~(g) Any financial arrangements related to the provision of pharmacy benefits management to the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.~~

~~150002. A pharmacy benefits manager shall disclose to a prospective purchaser in writing all of the following:~~

~~(a) The aggregate amount of all rebates and other retrospective utilization discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager.~~

~~(b) For a specified list of therapeutic classes, the aggregate amount for each therapeutic class of all rebates and other retrospective utilization discounts that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits specific to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A therapeutic class shall include at least two drugs.~~

~~(c) The nature, type, and amount of all other revenue that the pharmacy benefits manager estimates it would receive, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with prescription drug benefits related to the prospective purchaser, if that prospective purchaser were to contract with the pharmacy benefits manager. A pharmacy benefits manager shall not be required to disclose the purchase discounts based upon invoiced purchase terms for prescription drugs purchased directly or indirectly from a pharmaceutical manufacturer or labeler for sale and distribution through the mail order pharmacy of the pharmacy benefits manager.~~

~~(d) Any administrative or other fees charged by the pharmacy benefits manager to the prospective purchaser.~~

~~(e) Any arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy~~

~~benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.~~

~~150003. (a) A pharmacy benefits manager shall provide the information described in Section 150001 no less frequently than on a quarterly basis.~~

~~(b) Except for utilization information, a pharmacy benefits manager need not make the disclosures required in Sections 150001 and 150002 unless and until the purchaser or prospective purchaser agrees in writing to maintain as confidential any proprietary information. That agreement may provide for equitable and legal remedies in the event of a violation of the agreement. That agreement may also include persons or entities with whom the purchaser or prospective purchaser contracts to provide consultation regarding pharmacy services. Proprietary information includes trade secrets, and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers and personnel held by a pharmacy benefits manager and used for its business purposes.~~

~~150004. A pharmacy benefits manager may not execute a contract for the provision of pharmacy benefits management services that fails to address the following items:~~

~~(a) The amount of the total revenues, rebates, and discounts identified in subdivisions (a), (b), and (c) of Section 150001 and subdivisions (a), (b), and (c) of Section 150002 that shall be passed on to the purchaser.~~

~~(b) The disclosure or sale of enrollee utilization data by the pharmacy benefits manager to any person or entity other than the purchaser.~~

~~(c) Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.~~

~~(d) Conditions under which an audit will be conducted of the contract for pharmacy benefits management services, who will conduct the audit, and who will pay for the audit.~~

~~(e) Any revenues, rebates, or discounts received by the pharmacy benefits manager directly or indirectly from entities other than manufacturers and labelers that are related to the services to be provided to the purchaser.~~

~~(f) The process for development of formularies and notification of changes to formularies, and approval of those changes by the purchaser, provided that the pharmacy benefits~~

~~manager meets the requirements of Sections 150005, 150006, and 150007.~~

~~(g) Whether there is a difference between the price paid to a retail pharmacy and the amount that will be billed to the purchaser for prescription drugs.~~

~~150005. (a) All members of a pharmacy and therapeutics committee for a pharmacy benefits manager shall be physicians, pharmacists, academics, or other health care professionals, and a majority of committee members shall not be employed by the pharmacy benefits manager.~~

~~(b) A pharmacy and therapeutics committee member shall not be an officer, employee, director, or agent of, or any person who has financial interest in, other than ownership of stock from open market purchases of less than a nominal amount of the outstanding stock of, pharmaceutical companies.~~

~~150006. (a) Except as provided in subdivision (b), any request from a pharmacy benefits manager to a prescriber for authorization to substitute a medication shall include all of the following disclosures:~~

~~(1) The cost savings for the purchaser, if any, that are a result of the medication substitution.~~

~~(2) The difference, if any, in copayments or other out-of-pocket costs paid by the patient in order to obtain the medication.~~

~~(3) The existence of additional payments received by the pharmacy benefits manager that are not reflected in the cost savings to the purchaser.~~

~~(4) The circumstances, if any, under which the currently prescribed medication will be covered.~~

~~(5) The circumstances and extent to which, if any, related health care costs arising from the medication substitution will be compensated.~~

~~(6) Any known differences in potential effects on a patient's health and safety, including side effects.~~

~~(b) A pharmacy benefits manager shall not be required to make the disclosures required by subdivision (a) under any of the following instances:~~

~~(1) The substitution is from a brand drug to a generic or chemical equivalent in accordance with applicable state law.~~

~~(2) The medication substitution is initiated for patient safety reasons.~~

~~(3) The currently prescribed medication is no longer available in the market.~~

~~(4) The substitution is initiated pursuant to a drug utilization review.~~

~~(5) The substitution is required for coverage reasons where the prescribed drug is not covered by the patient's formulary or plan.~~

~~(c) A pharmacy benefits manager shall record the name and title of the prescriber, or the person other than the prescriber, authorizing the medication substitution if the authorization is given verbally.~~

~~(d) The pharmacy benefits manager shall not substitute a medication for a currently prescribed medication unless the pharmacy benefits manager communicates with the patient to provide that patient or their representative the following information:~~

~~(1) The proposed medication and the currently prescribed medication.~~

~~(2) The difference in copayments or other out-of-pocket costs paid by the patient, if any.~~

~~(3) Potential side effects of the medication substitution.~~

~~(4) The circumstances, if any, under which the currently prescribed medication will be covered.~~

~~(5) The circumstances and the extent to which, if any, health care costs related to the medication substitution will be compensated.~~

~~(6) Notification that the patient may decline the medication substitution if the currently prescribed drug remains on the patient's formulary, and the patient is willing to pay any difference in the copayment amount.~~

~~(7) A toll-free telephone number to communicate with the pharmacy benefits manager.~~

~~(e) The pharmacy benefits manager shall cancel and reverse the medication substitution upon written or verbal instructions from a prescriber or the patient. The pharmacy benefits manager shall not be required to cancel and reverse the medication substitution if the prescribed drug is no longer on the purchaser's formulary or the patient is unwilling to pay a higher copayment or other cost associated with the prescribed drug.~~

~~(f) The pharmacy benefits manager shall maintain a toll-free telephone number during normal business hours for a minimum of eight hours per day Monday through Friday for prescribers and patients.~~

~~(g) The pharmacy benefits manager shall not charge the individual any additional copayments or fees related to the replacement medication.~~

~~150007. A pharmacy benefits manager shall monitor the health effects on patients of medication substitutions requested by the pharmacy benefits manager. The pharmacy benefits manager shall, on a quarterly basis, report to his or her Pharmacy and Therapeutics Committee the results of the monitoring. This report shall include all patient and prescriber communications received by the pharmacy benefits manager that concern the efficacy or health effects of the medication substitutions.~~

~~150008. All disclosures made pursuant to this division shall comply with the privacy standards of the federal Health Insurance Portability and Accountability Act.~~

150001. (a) The contract entered into between the pharmacy benefits manager and the purchaser shall include both of the following:

(1) A disclosure in writing of any fees to be charged for drug utilization reports requested by the purchaser.

(2) The terms of confidentiality for any information received by the purchaser pursuant to subdivision (b).

(b) Except as provided in Section 150002, a pharmacy benefits manager shall provide all of the following information no less frequently than once each year and, at the request of the purchaser, within 30 days of receipt of the request by the purchaser:

(1) The aggregate amount, for a list of drugs to be specified in the contract, of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with the purchasing or dispensing of prescription drugs for individuals receiving under the purchaser's contract.

(2) The nature, type, and amount of all revenue the pharmacy benefits manager receives, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided by the pharmacy benefits manager with

respect to programs that the purchaser contracts with the pharmaceutical benefits manager to provide.

(3) Any prescription drug utilization information requested by the purchaser relating to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

(c) Any financial arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(d) Any financial arrangements related to the provision of pharmacy benefits management for the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

150002. (a) A pharmacy benefits manager is not required to make the disclosures required in Section 150001 unless and until the purchaser agrees in writing to maintain the disclosed information as confidential proprietary information. The agreement may provide for equitable and legal remedies in the event of a violation of this confidentiality provision. The agreement may authorize the purchaser to disclose the confidential proprietary information to persons or entities with whom the purchaser or prospective purchaser contracts to provide consultation regarding pharmacy services and may require those persons or entities to treat the information as confidential proprietary information.

(b) For purposes of this section, "proprietary information" includes trade secrets and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a pharmacy benefits manager and used for its business purposes.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 78 **VERSION: AMENDED APRIL 5, 2005**

AUTHOR: PAVLEY **SPONSOR: PAVLEY**

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACY BENEFIT MANAGEMENT

Existing Law:

Provides for the regulation of HMOs and the benefits they provide by the Department of Managed Health Care.

This Bill:

1) Defines "labeler" as any person who repackages prescription drugs for later sale and who has a labeler code issued by the Food and Drug Administration (FDA). (H&S 150000 Added)

2) Defines "pharmacy benefits management" as the administration or management of prescription drug benefits including:

a. The procurement of prescription drugs at a negotiated rate for dispensing,

b. The processing of prescription drug claims,

c. The administration of payments related to prescription drug claims.

(H&S 150000 Added)

3) Defines "pharmacy benefits manager" (PBM) as an entity that performs "pharmacy benefits management" as defined. (H&S 150000 Added)

4) Exempts health care service plans or health insurers if they perform pharmacy benefits management directly, or through a subsidiary, exclusively for their enrollees or insureds. (H&S 150000 Added)

5) Defines "purchaser" as any entity that enters into an agreement with a PBM for the provisions of pharmacy benefit management services. (H&S 150000 Added)

6) Defines "proprietary information" to include trade secretes and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a pharmacy PBM and used for its business purposes. (H&S 150002 Added)

7) Requires contracts entered into between a PBM and a purchaser to include:

a. A disclosure in writing of any fees to be charged fro drug utilization reports requested by the purchaser; and

b. The terms of confidentiality for any information received by the purchaser.

(H&S 150001 Added)

8) Requires a PBM to disclose to the purchaser the following, no less than once a year, and at the request of the purchaser, within 30 days of the request:

a. The aggregate amount of all rebates that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.

b. The nature, type, and amount of all other revenue that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.

c. Any prescription drug utilization information related to the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

d. Any arrangements with prescribers, medical groups, individual practice associations, or pharmacists that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

e. Any financial arrangements related to the provision of pharmacy benefits management to the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

(H&S 150001 Added)

9) Allows a PBM not to disclose required information in H&S 150001 unless a purchaser agrees in writing to maintain the disclosed information confidential and proprietary information. The agreement may provide for equitable and legal remedies in the event of a violation of the confidentiality provision. (H&S 150002 Added)

Comment:

1) Author's Intent. According to the author, this bill is needed to create consumer protection guidelines that PBMs must meet when doing business with California clients such as CalPERS, large employers, health plans, and union trust funds. The author believes that creating a more transparent market will shine a light on an industry that discloses an inadequate amount of pricing and conflict of interest information and will enable clients to make informed decisions about the type of prescriptions and benefits they select on behalf of their enrollees. According to the author, this will allow clients to take full advantage of the free market by incentivizing PBMs to compete in a fair, transparent environment for California business.

2) PBM Task Force. The board convened a task force on PBM regulation in 2003. The task force conducted a thorough evaluation of PBM practices to determine whether establishing state regulation of PBMs was necessary. The task force was unable to identify a clear need for regulation of PBMs. The task force was unable to define an existing or potential consumer harm that could be remedied by the regulation of PBMs. The areas of greatest potential concern, as expressed by participants, were related to the business and contractual relationships between PBMs and their clients (health plans, employers, trust funds, etc.) that would be best resolved by those parties in their negotiations.

3) State Legislation. AB 1960 (Pavley 2004), Pharmacy Benefit Management, was introduced last session and passed through the Legislature. Governor vetoed the bill. In his veto message the Governor stated "this measure would have the unintended consequence of increasing drug costs to health plans, the Medi-Cal Program and other purchasers, without providing any real consumer benefit. Studies, including one from the Federal Trade Commission, have shown that enactment of this legislation will limit competition and significantly increase the cost of prescription drugs."

4) Other States: Maine's law was the first of its kind. Shortly after passage, the law was challenged in the courts by the Pharmaceutical Care Management Association. The lawsuit

claimed that Maine's Unfair Prescription Drug Practices Act is preempted by federal law, would effect a regulatory taking of trade secrets and revenues, and violates due process, freedom of speech and the Commerce Clause of the Constitution.

States that rejected PBM disclosure laws in 2004 include California, Florida, Iowa, Kansas Maryland, Minnesota, Mississippi, New York, Vermont and Washington, the association said.

5) History.

2005

Apr. 14	From committee: Amend, do pass as amended, and re-refer to Com. On B. & P. (Ayes 10. Noes 4.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print. (Corrected January 10.)

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BILL ANALYSIS
AB 78

Date of Hearing: April 12, 2005

ASSEMBLY COMMITTEE ON HEALTH
Wilma Chan, Chair
AB 78 (Pavley) - As Amended: April 5, 2005

SUBJECT : Pharmacy benefits management.

SUMMARY : Requires specified disclosures related to contracts between a pharmacy benefits manager (PBM) and a purchaser of a PBM's service. Specifically, this bill :

1)Requires the contract entered into between a PBM and a purchaser of a PBM's service to include both of the following:

a) A disclosure in writing of any fees to be charged for drug utilization reports requested by the purchaser; and,

b) The terms of confidentiality for any information received by the purchaser pursuant to #2) below.

2)Requires a PBM to provide all of the following information no less frequently than once each year and, at the request of the purchaser, within 30 days of receipt of the request by the purchaser, except as provided in #3) below:

a) The aggregate amount, for a list of specified drugs, of all rebates and other utilization discounts that the PBM receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with the purchasing or dispensing of prescription drugs for individuals receiving drugs under the purchaser's contract;

b) The nature, type, and amount of all revenue the PBM receives, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided by the PBM with respect to programs that the purchaser contracts with the PBM to provide;

c) Any prescription drug utilization information requested by the purchaser relating to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser;

d) Any financial arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the PBM to encourage formulary compliance or

otherwise manage prescription drug benefits; and,

e) Any financial arrangements related to the provision of PBM services for the purchaser that exist between the PBM and any brokers, consultants, consulting companies, or other intermediaries.

3)States a PBM is not required to make the disclosures required in #2) above unless and until the purchaser agrees in writing to maintain the disclosed information as confidential proprietary information. States the agreement may provide for equitable and legal remedies and may authorize the purchaser to disclose the confidential proprietary information to persons or entities with which the purchaser or prospective purchaser contracts to provide consultation regarding pharmacy services and may require those persons or entities to treat the information as confidential proprietary information.

4)Defines for purposes of this bill, the following terms: labeler, pharmacy benefit management, pharmacy benefit manager, purchaser, and proprietary information.

EXISTING LAW provides for the regulation of health care benefits.

FISCAL EFFECT : Unknown.

COMMENTS :

1)PURPOSE OF THIS BILL . According to the author, this bill is needed to provide transparency in PBM contracts with their clients. The author notes that CalPERS and other large employers in the state use PBMs to manage their prescription drug benefits. According to the author, since the late 1990s, PBMs have been investigated and sued by state governments, consumer and labor groups, the Federal Trade Commission and the U.S. Justice Department. These investigations have targeted the refusal of PBMs to disclose the payments they receive from drug manufacturers and the practice of "drug switching" whereby PBMs steer customers towards more expensive drugs promoted by drug manufacturers. Most recently, on August 4, 2004, New York Attorney General Elliot Spitzer sued Express Scripts Inc. alleging the company pocketed as much as $100 million in drug rebates that should have gone to the state. In April 2004, State Attorney General Bill Lockyer and 19 other states attorneys generals reached a $29 million settlement with Medco, another PBM, after exposing Medco's relationships with drug manufacturers and the practice of drug switching whereby PBMs will shift patients to drugs, not for reasons or to save patients money, but instead to increase company profits. In 2003, the author reports PBM disclosure

bills were adopted in Maine and South Dakota. After PBMs claimed they would leave the South Dakota market as a result of those newly adopted disclosure provisions, eleven PBMs bid for the state's employee prescription drug contract using the disclosure guidelines. The author states that South Dakota ended up achieving an estimated 8% savings on its state funded health plan and notes that an 8% savings in California could reduce CalPERS prescription drug expenditures by over $18 million annually.

2)BACKGROUND . PBMs are independent specialty administrators; they focus on administering pharmacy benefits, and managing the purchasing, dispensing, and reimbursing of prescription drugs. According to the California Healthcare Foundation, about 45% of the U.S. population has pharmacy coverage provided directly by a PBM. PBMs offer health plans a variety of services including negotiating price discounts with retail pharmacies, negotiating rebates with manufacturers, and operating mail-order prescription services and administrative claims processing systems. PBMs also provide health plans with clinical services such as formulary development and management, prior authorization and drug utilization reviews to screen prescriptions for such issues as adverse interactions or therapy duplication, and substitution of generic drugs for therapeutically equivalent brand-name drugs. In order to provide these services, PBMs operate with multiple stakeholders in a complex set of relationships involving health plans, enrollees, pharmacies, and pharmaceutical manufacturers.

3)GENERAL ACCOUNTING OFFICE (GAO) REPORT ON PBMs . In January 2003, the federal General Accounting Office examined how PBMs participating in the federal employees' health program affect health plans, enrollees, and pharmacies. GAO's findings were generally positive. The PBMs produced savings for health plans by obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through mail-order pharmacies, passing on certain manufacturer rebates to the plans, and operating drug utilization control programs. GAO found the average price PBMs obtained from retail pharmacies for 14 brand name drugs was about 18% below the average price paid by customers without third-party coverage. Enrollees had wide access to retail pharmacies, coverage of most drugs, and benefited from cost savings generated by the PBMs. Pharmacy associations reported that PBMs' large market share leave some retail pharmacies with little leverage in negotiating with PBMs. In written responses to the report, one pharmacy association complained that the report did not address more broadly the economic relationships that exist in the PBM industry. Other critics complained that, as noted in its report, GAO did not independently verify information provide

by plans, PBMs or pharmacies.

4)COMPETITIVE CONCERNS AND PRICE TRANSPARENCY IN THE PBM MARKET .

In a September 2003 Food and Drug Law Institute Update, David Balto, formerly Director of Policy with the Bureau of Competition at the Federal Trade Commission, discussed concerns about the lack of transparency in the PBM industry. Balto stated that secret rebates can lead to discrimination that ultimately may harm purchasers and the ultimate consumer. Secret rebates may encourage a PBM to choose a higher priced drug with a higher rebate, instead of a lower priced drug, resulting in higher costs to consumers. Balto noted that the PBM market is highly concentrated with the four largest firms holding a combined 80% market share. Substantial costs have prevented any successful entry into the PBM market for some time and the cost to plan sponsors of switching PBMs deters such switching. Balto reports that a group of 21 state attorneys general is investigating anticompetitive conduct by the major PBMs. In California, the American Federation of State, County and Municipal Employees sued the nation's four largest PBMs alleging they violated California's unfair competition law.

5)JOINT FEDERAL TRADE COMMISSION (FTC)-DEPARTMENT OF JUSTICE (DOJ) REPORT ON COMPETITION . On July 23, 2004, the FTC and DOJ issued a joint report entitled Improving Health Care: A Dose of Competition . In that report, the FTC and DOJ recommended that states should consider the potential costs and benefits of regulating PBM transparency. According to the report, in general, vigorous competition, rather than regulation, in the marketplace for PBMs is more likely to arrive at an optimal level of transparency. The report continues, "Just as competitive forces encourage PBMs to offer their best price and service combinations to health-plan sponsors to gain access to subscribers, competition should also encourage disclosure of the information that health-plan sponsors require to decide which PBM to contract. " (emphasis added).

6)SUPPORT . Supporters argue that this bill will improve PBM transparency, reduce conflicts of interest by PBMs, and result in reduced drug costs to employers, government and patients. Supporters argue that the many investigations and law suits against PBMs, including the $29 million multistate settlement with Medco announced last year demonstrate a need to protect PBM clients and consumers.

7)OPPOSITION . Opponents argue that by requiring broad disclosure of prices negotiated between PBMs and drug manufacturers, manufacturers will be discouraged from offering

deep discounts when they believe that those discounts can not be kept confidential. Opponents also argue that the disclosures in this bill are impractical and in many cases impossible, especially the requirement to disclose rebates, discounts and other revenue received specific to the purchaser. Opponents cite a PriceWaterhouseCoopers study commissioned by the PBM industry which estimated that AB 1960 (Pavley) of 2003 would have increased prescription drug costs in California by 7%.

8)PREVIOUS LEGISLATION . AB 1960 would have required pharmacy PBMs to make various disclosures to purchasers of PBM services similar to this bill. AB 1960 also contained provisions related to prospective purchasers, contract requirements, pharmacy and therapeutics committees, and drug substitutions which are not in this bill. AB 1960 was vetoed by the Governor.

9)TECHNICAL CORRECTIONS :

a) On page 9, it appears that subdivisions (c) and (d) should be numbered paragraphs (4) and (5); and,

b) On page 9, line 24, it appears "or prospective purchaser" should be deleted because all references to prospective purchasers have been otherwise deleted from the April 5, 2005 version of this bill.

10)QUESTION . Does the disclosure of utilization information required by this bill protect enrollee privacy?

11)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Business and Professions Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

AIDS Healthcare Foundation
American Federation f State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Public Interest Research Group
California School Employees Association
Consumers Union
Health Access California
Older Women's League of California
Retired Public Employees Association
Screen Actors Guild
Service Employees International Union

Opposition

California Association of Health Plans
California Chamber of Commerce
Caremark
Express Scripts, Inc.
Health Net
Kaiser Permanente

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL No. 798

Introduced by Senator Simitian

February 22, 2005

An act to ~~amend Section 1357.51 of~~ *add Division 115 (commencing with Section 150000) to* the Health and Safety Code, relating to ~~health care service plans~~ *pharmaceuticals*.

LEGISLATIVE COUNSEL'S DIGEST

SB 798, as amended, Simitian. ~~Health care service plans: preexisting conditions~~ *Prescription drugs: collection and distribution program.*

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would specify requirements of a program established by a county under these provisions, including, among others, for procedures that ensure the proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist. The bill would authorize any drug manufacturer legally authorized under federal law to manufacture or sell pharmaceutical drugs, licensed health facility, or pharmacy to donate medications pursuant to these provisions.

~~Existing law provides for regulation of health care service plans by the Department of Managed Health Care. Existing law provides that a~~

~~plan contract that covers 3 or more enrollees may not exclude coverage for any individual on the basis of a preexisting condition for a period greater than 6 months following the individual's effective date of coverage.~~

~~This bill would change that time period from 6 to 8 months.~~

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. Section 1357.51 of the Health and Safety Code is amended to read:~~

SECTION 1. Division 115 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 115. SURPLUS MEDICATION COLLECTION AND DISTRIBUTION

150000. It is the intent of the Legislature in enacting this division to authorize the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

150002. A health facility licensed under Chapter 2 (commencing with Section 1250) of Division 2, a pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, and a drug manufacturer that is legally authorized under federal law to manufacture and sell pharmaceutical drugs, may donate excess or surplus unused prescribed medications under a program established by a county pursuant to this division.

150004. (a) A county may establish, by local ordinance, a repository and distribution program for purposes of this division.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist by ensuring, at a minimum, all of the following:

(A) That only those drugs that are received and maintained in their unopened, tamper-evident packaging are dispensed.

(B) That any drugs received have not been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia or the product manufacturer.

(C) That any drugs received are dispensed prior to their expiration date.

(D) That reasonable methods have been established to ensure that drugs received have not been in the possession of any individual member of the public.

(E) That a pharmacist may use his or her discretion and best judgment in deciding whether or not to accept any donated drug.

(F) That records are kept for at least three years from the date that any drug is received or dispensed, whichever is later, pursuant to this division.

~~1357.51. (a) No plan contract that covers three or more enrollees shall exclude coverage for any individual on the basis of a preexisting condition provision for a period greater than eight months following the individual's effective date of coverage. Preexisting condition provisions contained in plan contracts may relate only to conditions for which medical advice, diagnosis, care, or treatment, including use of prescription drugs, was recommended or received from a licensed health practitioner during the six months immediately preceding the effective date of coverage.~~

~~(b) No plan contract that covers one or two individuals shall exclude coverage on the basis of a preexisting condition provision for a period greater than 12 months following the individual's effective date of coverage, nor shall the plan limit or exclude coverage for a specific enrollee by type of illness, treatment, medical condition, or accident, except for satisfaction of a preexisting condition clause pursuant to this article. Preexisting condition provisions contained in plan contracts may~~

~~relate only to conditions for which medical advice, diagnosis, care, or treatment, including use of prescription drugs, was recommended or received from a licensed health practitioner during the 12 months immediately preceding the effective date of coverage.~~

~~(c) A plan that does not utilize a preexisting condition provision may impose a waiting or affiliation period not to exceed 60 days, before the coverage issued subject to this article shall become effective. During the waiting or affiliation period, the plan is not required to provide health care services and no premium shall be charged to the subscriber or enrollee.~~

~~(d) A plan that does not utilize a preexisting condition provision in plan contracts that cover one or two individuals may impose a contract provision excluding coverage for waivered conditions. No plan may exclude coverage on the basis of a waivered condition for a period greater than 12 months following the individual's effective date of coverage. A waivered condition provision contained in plan contracts may relate only to conditions for which medical advice, diagnosis, care, or treatment, including use of prescription drugs, was recommended or received from a licensed health practitioner during the 12 months immediately preceding the effective date of coverage.~~

~~(e) In determining whether a preexisting condition provision, a waivered condition provision, or a waiting or affiliation period applies to any enrollee, a plan shall credit the time the enrollee was covered under creditable coverage, provided that the enrollee becomes eligible for coverage under the succeeding plan contract within 62 days of termination of prior coverage, exclusive of any waiting or affiliation period, and applies for coverage under the succeeding plan within the applicable enrollment period. A plan shall also credit any time that an eligible employee must wait before enrolling in the plan, including any postenrollment or employer-imposed waiting or affiliation period.~~

~~However, if a person's employment has ended, the availability of health coverage offered through employment or sponsored by an employer has terminated, or an employer's contribution toward health coverage has terminated, a plan shall credit the time the person was covered under creditable coverage if the person becomes eligible for health coverage offered through employment or sponsored by an employer within 180 days,~~

~~exclusive of any waiting or affiliation period, and applies for coverage under the succeeding plan contract within the applicable enrollment period.~~

~~(f) No plan shall exclude late enrollees from coverage for more than 12 months from the date of the late enrollee's application for coverage. No plan shall require any premium or other periodic charge to be paid by or on behalf of a late enrollee during the period of exclusion from coverage permitted by this subdivision.~~

~~(g) A health care service plan issuing group coverage may not impose a preexisting condition exclusion upon the following:~~

~~(1) A newborn individual, who, as of the last day of the 30-day period beginning with the date of birth, has applied for coverage through the employer-sponsored plan.~~

~~(2) A child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning with the date of adoption or placement for adoption, is covered under creditable coverage and applies for coverage through the employer-sponsored plan. This provision shall not apply if, for 63 continuous days, the child is not covered under any creditable coverage.~~

~~(3) A condition relating to benefits for pregnancy or maternity care.~~

~~(h) An individual's period of creditable coverage shall be certified pursuant to subsection (e) of Section 2701 of Title XXVII of the federal Public Health Services Act (42 U.S.C. Sec. 300gg(e)).~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 798 **VERSION: AMENDED MARCH 29, 2005**

AUTHOR: SIMITIAN **SPONSOR: SIMITIAN**

RECOMMENDED POSITION: NO POSITION

SUBJECT: HEALTH CARE SERVICE PLANS: PREEXISTING CONDITIONS
PRESCRIPTION DRUGS: COLLECTION

Existing Law:

Pharmacy Law provides for the licensure and regulation of pharmacists by the board and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This Bill:

1) Authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. (H&S 150004 Added)

2) Requires a county that establishes a repository and distribution program would be required to establish procedures for all of the following:

a. Establishing eligibility for medically indigent patients who may participate in the program.

b. Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

c. Ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist by ensuring, at a minimum, all of the following:

i. That only those drugs that are received and maintained in their unopened, tamper evident packaging are dispensed.

ii. That any drugs received have not been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia or the product manufacturer.

iii. That any drugs received are dispensed prior to their expiration date.

iv. That reasonable methods have been established to ensure that drugs received have not been in the possession of any individual member of the public.

v. That a pharmacist may use his or her discretion and best judgment in deciding whether or not to accept any donated drug.

vi. That records are kept for at least three years from the date that any drug is received or dispensed, whichever is later, pursuant to this division.

(H&S 150004 Added)

3) Authorizes drug manufacturers to donate excess or surplus unused prescribed medications to programs established by counties. (H&S 15002 Added)

Comment:

1) Author's Intent. The author's intent is to provide another avenue for low income individuals to obtain prescription.

2) Concerns. Staff is concerned that this bill establishes a framework to offer, on a county by county basis, a program that should be offered statewide, and it vest writing, what should be statewide standard procedures, with individual counties that choose to participate in the program. If enacted this measure would result in a patchwork of individually run programs throughout the state with different eligibility requirements for recipients and different procedures for the pharmacies, drug manufacturers, and health facilities that wish to participate in the program. If California were to establish a prescription drug repository and distribution program, the state would be best served if it copied programs in other states that have established similar programs.

3) Other States. At least five other states have established drug repository and distribution programs; these are: Okalahoma, Missouri, South Dakota, Wisconsin, and Louisiana. While no two states' programs are exact, there are commonalities among the programs; these commonalties are:

a) Establishment of a statewide program with statewide procedures.

b) Regulations for the implement the program are written by either the state's Board of Pharmacy or Department of Health. Regulations include the following not present in SB 798:

   i. The issuance of a program identification card for eligible recipients of the program.

   ii. Establishment of a handling fee to be charge to recipients of the program.

c) A list of formulary of drugs or class of drugs accepted for donation to the program.

d) The exclusion of controlled dangerous drugs from the program.

e) A provision in the enabling legislation that pharmacists, pharmacies, health facilities, drug manufacturers, and state agencies that participate in the program will not be subject to criminal or civil liability for injury, death, or property, for participating in the program.

4) Amended on March 29, 2005. SB 798 was gutted and amended on March 29, 2005. The introduced version of the bill was a spot bill relating to managed health care.

5) History.

2005

Apr. 11	Set for hearing May 4.
Mar. 30	Withdrawn from committee. Re-referred to Com. on HEALTH.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 23	Set for hearing April 6.
Mar. 10	To Coms. on B., F. & I. and HEALTH
Feb. 24	From print. May be acted upon on or after March 26.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Legislation and Regulation Committee
Strategic Plan Update for April 2005

Goal 3:	**Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.**
Outcome:	**Improve the health and safety of Californians.**

Objective 3.1:	**Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.**
Measure:	**100 percent successful enactment of promoted legislative changes**
Tasks:	1. Secure extension of board's sunset date. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 3. Sponsor legislation to add enforcement options for non-compliance issues. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. **Advocacy: AB 320, AB 1826, AB 1960, AB 2184, AB 2660, AB 2682, SB 1159, AB 1196, SB 1427, SB 1563, SB 1735, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774** **Technical Assistance: AB 262, AB 746, AB 1196, AB 1957, AB 2125, SB 151, SB 175, SB 292, SB 361, SB 490, SB 545, SB 774, SB 907, SB 1149, SB 1333** 6. Sponsor clean-up language to B & P Code section 4312. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. **Public meetings held on March 27, 2003 and September 11, 2003. Public meeting held on March 30, 2004.** 8. Sponsor legislation to strengthen consumer protections in wholesale transactions. **Completed 9/29/2004 – Chapters 857 and 887, Statutes of 2004.**

	9. Sponsor legislation to address licensing issues related to the UC Davis Veterinary Medical Teaching Hospital. **Governor signed SB 1913 September 22, 2004.** 10. Sponsor legislation to define "compounding and establish standards for pharmacies that compound drug products for patients. **AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs. Introduced February 17, 2005.** 10. Support for Senate B&P Committee Omnibus bill that includes changes to the following code sections: **B&P 4005 & 4206, 4053, 4127.5, 4205 & 4400, 4231 & 4232, 4360-4373, 4023.5, 4038, 4114, 4115, 4115.5 & 4202, 4315, 4104** **SB 1111 (B&P Com.) Omnibus Bill. Introduced March 30, 2005.**

Objective 3.2: **Measure:**	**Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.** **Percentage successful enactment of promoted regulatory changes**
Tasks:	1. Strengthen standards for compounding sterile injectable drug products. **Completed. Regulation effective October 29, 2004.** 2. Authorize the executive officer the authority to issue citations and fines. **Completed. Regulation effective October 11, 2003.** 3. Eliminate the clerk typist ratio. **Completed. Regulation effective October 3, 2004.** 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. **Completed. Regulation effective October 2, 2004.** 5. Update pharmacy self-assessment form. **January 2005 – Board adopted** 6. Allow central filling by hospital pharmacies. **Completed. Regulation effective October 22, 2004.** 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. **Completed. Regulation effective October 22, 2004.** 8. Modify patient notification provision of the quality assurance regulation to require notification only if the error results in the medication being administered to the patient or a clinically significant delay in therapy. **Completed. Regulation effective October 22, 2004.** 9. Require pharmacies using a common electronic file to adopt

	policies to ensure confidentiality of patient information. **Completed. Regulation effective October 22, 2004.** 10. Update pharmacy technician regulations to conform to SB 361. **Completed. Regulation effective October 22, 2004.** 11. Update pharmacist licensure regulations to conform to SB 361. **Completed. Regulation effective October 22, 2004.** 12. Complete a Section 100 filing to clean up regulations in conformity with recent legislation. 13. Omnibus rule making package covering the following areas: abandonment of application files, pharmacist identification, pharmacy self assessment, pharmacy practice, recognized schools of pharmacy, application of pharmacist examination and licensure, supervision of intern pharmacists, intern pharmacist, requirements for examination, pharmacist candidates, continuing education, fees, partial filling of schedule II prescriptions, foreign graduates. **January 2005 – Board adopted**

Objective 3.3: **Measure:**	**Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.** **Number of areas of pharmacy law reviewed**
Tasks:	1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. **Completed – Chapter 250, Statutes of 2003 (SB 175)** 3. Evaluate group dispensing by prescribers. **August 2003 - Draft legislation developed in concert with the Medical Board. Awaiting board action.** 4. Evaluate pharmacist intern statutes and regulations. **December 2003 – Draft legislation and regulations prepared and presented to the Licensing Committee.** **January 2004 – Draft legislation and regulations approved by the board.** **February 2004 – Rulemaking noticed on approved regulations.** **March 2004 – Statutory provisions introduced in SB 1913.** **Governor signed SB 1913 on September 22, 2004.** 5. Evaluated out of state distributor requirements. **Completed – Chapter 725, Statutes of 2004 (AB 2628)** **Completed – Chapter 857, Statutes of 2004 (SB 1307)** 6. Evaluated clinic licensing. **March 2005 – Initiated.**

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MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: APRIL 7, 2005
LOCATION: DEPARTMENT OF CONSUMER AFFAIRS
400 R STREET, SUITE 4070
SACRAMENTO, CA 95814
9:30 A.M. – 1:30 P.M

BOARD MEMBERS PRESENT:

JOHN JONES, CHAIR
KENETH SCHELL

BOARD STAFF PRESENT:

PATRICIA HARRIS
VIRGINIA HEROLD
JAN PEREZ

The meeting was convened at 9:30 a.m.

Legislation

The committee was provided with a list of bills and bill analysis, which it reviewed. While the discussion was lively at times, the board chose to take positions on only a few bill and directed staff to watch bills on which it took no position. The bills the committee discussed and the positions the committee recommended are as follows:

AB 595 (Negrete McLeod) Pharmacy: Compounding Of Prescription Drugs.
This bill is sponsored by the board to define "compounding" and to provide direction for regulations that will follow later this year. The board approved draft legislation at its January 2005 meeting.
Recommended Position: Support

Bills of Interest

AB 21 (Levine) Pharmacists: Contraceptive Devices.
Version: Amended 3/29/05
Recommended Position:

AB 71 (Chan) Pharmaceuticals: Adverse Drug Reac.: Office Of Ca. Drug Safety Watch.
Version: Amended 2/11/05
Recommended Position: No Position

AB 72 (Frommer) Prescription Drugs: Manufacturer Reporting Requirement.
Version: Introduced
Recommended Position: No Position

AB 73 (Frommer) Prescription Drugs: Importation: Procurement.
Version: Introduced
Recommended Position: No Position

AB 74 (Gordon) California Rx Prescription Drug Hotline.
Version: Introduced
Recommended Position: Oppose Unless Amended
Recommended Amendments: 1) Require people staffing the Hotline to refer callers to legal sources for obtaining prescription drugs and specify that it is illegal to import drugs from outside the United States. 2) Require people staffing the Hotline to discuss the importance of one pharmacist reviewing all the medications a patient is taking, and if a person obtains their medications from multiple sources the person should seek out a pharmacist that can review all their medications. 3) Specify that the price comparison of 50 commonly prescribed drugs be based on both the Medi-Cal price and cash price paid for prescription drugs.

AB 75 (Frommer) Pharmaceutical Assistance Program.
Version: Amended 4/5/05
Recommended Position:

AB 76 (Frommer) Office of Pharmaceutical Purchasing.
Version: Introduced
Recommended Position: No Position

AB 78 (Pavley) Pharmacy Benefits Management.
Version: Amended 4/5/05
Recommended Position: No Position

AB 225 (Negrete McLeod) Electronic Prescription Information.
Version: Introduced
Recommended Position: Support if Amended
Recommended Amendment: The prescriber, prior to the electronic transmitting of a prescription, offers to transmit the prescription to a pharmacy of the patient's choice.

AB 283 (Koretz) Pseudoephedrine: Retail Sale.
Version: Introduced
Recommended Position: Oppose

AB 288 (Mountjoy) Pharmacies: Prescription Containers: Labels.
Version: Introduced
Recommended Position:

AB 497 (Negrete McLeod) Drug Wholesalers And Manufacturers: Licensure Exemption.
Version: Amended 4/5/05
Recommended Position: Oppose

AB 522 (Plescia) Automated Drug Delivery System.
Version: Amended 3/29/05
Recommended Position: Support if Amended
Recommended Amendments: Add the words "and dosage" to page 3, line 37 to read: "After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug and dosage as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient."

AB 657 (Karnette) Pharmacies: Prescription Containers.
Version: Amended 4/5/05
Recommended Position: Support

AB 896 (Matthews) Clinical Laboratories.
Version: Introduced
Recommended Position: Support

AB 1370 (Matthews) Clinical Laboratory Director: Pharmacists.
Version: Introduced
Recommended Position: Support

SB 19 (Ortiz) California Rx Program.
Version: Amended 1/6/05
Recommended Position:

SB 152 (Speier) Pseudoephedrine.
Version: Introduced
Recommended Position: Oppose

SB 380 (Alquist) Drugs: Adverse Event Reporting.
Version: Introduced
Recommended Position: No Position

SB 401 (Ortiz) Medical information: pharmacies: marketing.
Version: Amended 4/4/05
Recommended Position: Support if Amended
Recommended Amendment: Require written information that is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs, to be labeled as an advertisement.

SB 592 (Aanestad) Acute care hospitals: inpatient pharmacy technician services.
Version: Amended 3/29/05
Recommended Position: Support

SB 644 (Ortiz) Dispensing of prescriptions.
Version: Introduced
Recommended Position:

SB 734 (Torlakson) Controlled substances.
Version: Introduced
Recommended Position: Oppose Unless Amended
Recommended Amendments: 1) Add a provision that would effectively cap board's funding of CURES each year unless the board receives an appropriation augmentation sufficient to cover the additional cost billed by the DOJ. 2) Delete the requirement that the privileges of a practitioner to prescribe controlled substances be printed on the prescription form. (Page 10, lines 10-19). 3) Delete the requirement that a pharmacist must report to the DOJ the method of payment used by a customer when purchasing Schedule II and III drugs. (Page 13, line 5).

SB 798 (Simitian) Prescription Drugs: Collection And Distribution Program
Version: Amended 3/29/05
Recommended Position:

Regulations Update

The committee was provided with the board's 2005 Rulemaking Calendar. No discussion. See attachment 1.

Proposed Initiative Update

Staff noted that In January 2005, the Secretary of State requested the board analyze three proposed initiatives relating to prescription drugs. The proposed initiatives and the board's draft analysis of the initiatives were available for the boar member's review. No discussion.

Adjournment

The committee adjourned at 1:30 p.m.

Attachment 1

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BOARD OF PHARMACY
2005 RULEMAKING CALENDAR

SCHEDULE A: PROPOSED REGULATIONS IMPLEMENTING STATUTES ENACTED DURING THE YEAR 2004

Subject:	CCR Title & Sections Affected:	Statutes Being Implemented:
Pharmaceutical Practices	Title 16, Amend Section 1717e Adopt Section 1712	SB 1913

Responsible Agency Unit:	Contact Person & Phone Number:	Projected Dates:			
		Notice:	Hearing:	Adoption:	To OAL:
Board of Pharmacy	Jan E. Perez, (916) 445-5014	07/2005	10/2005	10/2005	12/2005

Subject:	CCR Title & Sections Affected:	Statutes Being Implemented:
Delivery of Prescriptions	Title 16, Add Section 1713	None.

Responsible Agency Unit:	Contact Person & Phone Number:	Projected Dates:			
		Notice:	Hearing:	Adoption:	To OAL:
Board of Pharmacy	Jan E. Perez, (916) 445-5014	10/2005	01/2006	01/2006	03/2006

Subject:	CCR Title & Sections Affected:	Statutes Being Implemented:
Compounding	Title 16, Repeal Sections 1716.1, 1716.2 Add Sections 1735-1735.7	None.

Responsible Agency Unit:	Contact Person & Phone Number:	Projected Dates:			
		Notice:	Hearing:	Adoption:	To OAL:
Board of Pharmacy	Jan E. Perez, (916) 445-5014	11/2005	01/2006	01/2006	04/2005

BOARD OF PHARMACY
2005 RULEMAKING CALENDAR

SCHEDULE B: PROPOSED REGULATIONS IMPLEMENTING STATUTES ENACTED PRIOR TO THE YEAR 2004

<table>
<tr><td colspan="2">Subject:</td><td colspan="2">CCR Title & Sections Affected:</td><td colspan="4">Statutes Being Implemented:</td></tr>
<tr><td>Responsible Agency Unit:
Board of Pharmacy</td><td colspan="2">Contact Person & Phone Number:
Jan E. Perez (916) 445-5014 x 4016</td><td colspan="4">Projected Dates:</td></tr>
<tr><td></td><td></td><td>Notice:</td><td>Hearing:</td><td>Adoption:</td><td>To OAL:</td></tr>
<tr><td colspan="6">Report on the status of all uncompleted rulemaking described on previous calendars:

Self Assessment of a Pharmacy by the Pharmacist in Charge, Title 16 Section 1715- Adopted 01/20/05 – to OAL April 2005

Application for Pharmacist Examination and Licensure, Title 16 Section 1720 - Adopted 01/20/05 – to OAL April 2005

Fee Schedule, Title 16 Section 1749 - Adopted 01/20/05 – to OAL April 2005</td></tr>
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California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LEGISLATION AND REGULATION COMMITTEE

Regulation Report

NO ACTION

Regulation Update

Rulemaking Activity

Staff published a 15-day notice on February 2, 2005 to make minor change to the omnibus group of regulations approved by the board at the January 2005 board meeting. That notice period ended on February 22, 2005. There were no changes or comments to made to this language.

The rulemaking package is now undergoing administrative review. The regulations should be in place before the July 2005 board meeting. A copy of the language is provided in Attachment 1.

Pending Regulations

At the October 2004 Board meeting, the board moved to regulation hearing proposed regulation changes that will permit the use of drop boxes to drop off prescriptions, and the use of automated dispensing devises to dispense refill medication when the patient has "opt-in" to use this system. At the current time, the regulation has not been noticed. A copy of the language is provided in Attachment 2.